

Award Number: W81XWH-10-1-1044

TITLE: Obesity/Overweight in Persons with Early and Chronic SCI: A Randomized Multi-Center Controlled Lifestyle Intervention

PRINCIPAL INVESTIGATOR: Mark S. Nash, Ph.D.

CONTRACTING ORGANIZATION: University of Miami Miller School of Medicine
Miami, Florida 33136

REPORT DATE: October 2012

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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4. TITLE AND SUBTITLE Obesity/Overweight in Persons with Early and Chronic SCI: A Randomized, Multicenter, Controlled Lifestyle Intervention				5a. CONTRACT NUMBER À	
				5b. GRANT NUMBER Y FYYP E-€€€€ I	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Mark S. Nash, Ph.D., FACSM, PI				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Miami Miller School of Medicine Miami, FL 33136				8. PERFORMING ORGANIZATION REPORT NUMBER	
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13. SUPPLEMENTARY NOTES					
14. ABSTRACT The study continuing report was approved by the IRB on 20 June 2012. For the Miami site we have screened and consented a total of 14 individuals for this study. After passing the initial screening, four enrolled individuals [paraplegia (n=3) and tetraplegia (n=1)] satisfied the study inclusion criteria. The Atlanta site has screened three qualifying individuals, one is enrolled and one currently undergoing additional cardiac testing for an abnormal ECG finding. The single screening failure was for normal fasting glucose. The 3 enrolled paraplegic participants (aged 58 ±10.7 yrs [mean ± s.d.], duration of injury 12.8±14.4 yrs. and % Body Fat of 34.4 ± 6.5 % have been randomized to the exercise training plus dietary/behavioral intervention study arm. Results to date show that following 3 month of exercise training and dietary/behavioral intervention, average body mass is reduced by over 4% compared to baseline results, which is a benefit of 57% toward the primary study outcome target of 7% reduction in overall body mass. Dynamic upper extremity strength gains were observed in all exercise maneuvers, ranging from 9-37%, with the largest improvement observed in both dip and overhead press maneuvers. Overall strength increase (Sum of 1RM value) was 26% greater following 3-months study participation. Fasting plasma Insulin Sensitivity Index (ISI) was increased by 85%, HOMA Insulin Resistance (IR) and HbA1C were decreased by 38% and 5%, respectively, all substantial improvements in these markers of diabetes risk. Total cholesterol was reduced by 7.5 %, and HDL and LDL were reduced by ~6 and 11%, respectively. In general, these early findings are consistent with both hypothesized benefits of intervention and clinically significant benefits.					
15. SUBJECT TERMS Spinal cord injuries, dyslipidemia, diabetes prevention, exercise, diet, behavior					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 436	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

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Section I – Introduction

The overarching study objective is to reduce health hazards from an overweight/obese body habitus and co-morbid cardiometabolic disorders in people with SCI, and to improve their life quality. The study is a four-year multi-center randomized clinical trial (RCT) conducted at 2 SCI rehabilitation research centers and two Veterans Affairs Medical Centers. The study is modeled after the Diabetes Prevention Program (DPP), an NIH-sponsored 27-center RCT that reported a sustained 7% body weight reduction in pre-diabetic individuals accompanied by a 58% decrease in progression to type-2 diabetes. The lifestyle intervention approach incorporating diet, exercise, and behavioral adjustments was more effective than pharmacotherapy, benefited both genders and persons of all races, and has lasted 10 years after initiation.

The study plan will enroll 90 persons with SCI who are overweight/obese and have fasting atherogenic dyslipidemia and dysglycemia. Interventions will include 6 months of structured lifestyle intervention incorporating education, exercise, diet, and behavioral support. A second arm will test benefits of exercise alone while controlling for investigator contact. Multiple baselines tested before intervention will serve as a treatment control.

Exercise will include a six-month circuit resistance training program already established as effective in fitness attainment for persons with paraplegia and tetraplegia. Dietary intervention over the same period will balance caloric expenditure measured by indirect calorimetry and food intake, the latter coming from a Mediterranean style diet having effectiveness established in the DPP for durable weight loss and diabetes prevention. The investigators and personal ‘lifestyle coaches’ will then shape and follow client-specific exercise and diet programs to be conducted for 12 months in the home or community-based centers. Behavioral approaches will include a 16-week training curriculum presented in both small groups and with the lifestyle coaches. Other behavioral approaches will include customized trial information booklets, performance incentives, outcome challenges between centers, and use of the VA Telehealth system for performance tracking, compliance assessment, and motivational support.

Study specific aims and their accompanying hypotheses will test effects of intervention on: 1) reducing body weight and radiographically-derived body fat, 2) improving fitness as assessed by endurance, strength, and anaerobic power, 3) reducing risks of fasting dyslipidemia, post-prandial lipemia, and insulin resistance, and 4) enhancing perceived health-related quality of life. Data will be analyzed by Multivariate analysis with repeated measures. Ancillary testing will investigate effects of intervention on the whole body oxidation of fat at rest and following food intake, and examine the relationship between dietary intake and caloric expenditure at the beginning and the end of the 18 month study. The primary trial goal pays fidelity to the DPP by targeting sustained loss of 7% of body weight, a proven countermeasure for prevention of diabetes.

Section II – Body

- 1) IRB continuing approvals have been obtained from all study sites.
- 2) The study database has been approved by the Miami-VAMC and is fully operational at both the primary and secondary sites.
- 3) All equipment has been placed, in-serviced, and is in use for assessments. Training of research subjects is active
- 4) The clinical pathway for the Tele Health system has been deployed and is in use for subjects who have reached the extension phase of the study.
- 5) Team meetings have been held according to schedule and the secondary site has been site visited.
- 6) Unanticipated numbers off screening failures in both sites are currently being tracked for possible modification of qualifying subject characteristics.

Section III – Key Research Accomplishments

Key Research Accomplishments: Bulleted list of key research accomplishments emanating from this research.

- Completion of the population-specific:
 - Clinical Trial Manual (Appended)
 - Nutritional Manual Supplement (Appended)
 - Participant Lifestyle Manual / Lifestyle Balance Notebook (Appended)
 - Intake Form
 - Inclusion/Exclusion Check off :DOD Trial Manual (pdf): pp 5-6
 - Telehealth Clinical Pathway for "Obesity/Overweight": DOD Trial Manual (pdf): pp 159
 - DPP Lifestyle Materials for Sessions 1-16 (Adapted for SCI): DOD Trial Manual (pdf): pp51-156
 - Lifestyle Coach Materials: Lifestyle Coaches Manual (pdf)
 - Optional Participant Handouts: Fact Counter (pdf) / Keeping Track (pdf)
 - Complete Dietary Packets for 1200, 1500, 1800, and 200 kcal
- Deployment of the study data repository and data analysis system
- Deployment of the TeleHealth Module for subjects entering the extension phase
- Reportable Outcomes (See Section IV)

Section IV – Reportable Outcomes

Presentations incorporating information from this award:

Juried Manuscript

Nash, M.S., R.E. Cowan, and J. Kressler. "Evidence-based and Heuristic Approaches for Customization of Care in Cardiometabolic Syndrome after SCI. *J Spinal Cord Med* 35(5):278-92, 2012.

Peer-Review Abstracts

Bigford, G.E., L. Brooks, P.A. Burns-Drecq, C. Kappy, K. Kreger, R. Munoz, D. Backus, and M.S. Nash. A Population-Relevant Lifestyle-Intensive Intervention for Diabetes Prevention after SCI. *Top Spinal Cord Inj Rehabil* (In Press) May, 2013.

Nash, M.S., G.E. Bigford, L. Brooks, P.A. Burns-Drecq, C. Kappy, K. Kreger, CCRP; R. Munoz, and D. Backus. Intensive Lifestyle Intervention after Paraplegia Significantly Reduces Cardiometabolic Risks: A Two-Subject Case Report. *Top Spinal Cord Inj Rehabil* (In Press) May, 2013.

Presentations at National/International Conference

Best Practices in Cardiometabolic Disease Management after SCI: Is Guideline-Driven Treatment Sufficient? Summit 2011 + EXPO: Delivering Excellence, Achieving State-of-the-Art Health Care. Paralyzed Veterans of America, Orlando, FL, September 2011.

Cardiometabolic Disease in the Aging Person with Spinal Cord Injury: An Evidence-Based Approach. Annual Assembly, American Academy of Physical Medicine & Rehabilitation. Orlando, FL, November 2011.

Spinal Cord Injury: Evidence-based and Heuristic Approaches to Customization of Care for Cardiometabolic Syndrome [Keynote]. 5th Canadian National Spinal Cord Injury Conference: Translating Neural Engineering and Novel Therapies, Toronto, Canada, September 2012.

Section V – Conclusion

Trial preparation as outlined in the scope of work has been completed and work initiated within the past year. Continuing reports to local ethical authorities have been approved at all sites. All equipment and study manuals are in current use. No adverse events or serious adverse events have been experienced. TeleHealth modules have been deployed. Subjects have been recruited, qualified, and are currently undergoing described interventions; subjects have now entered the extension phase of intervention. Outcome data are sufficient to justify presentation at the national meeting of the American Spinal Injury Association, and to earn designation by the Research Committee as “award eligible” for the upcoming conference.

Unavoidable delays imposed by the Veterans Administration for use of the study database have been overcome. Benefits of the intervention in the form of significant weight loss and improved health are obvious, consistent with hypothesized benefits, and self-reinforcing among the study subjects. A site visit to the subcontractor confirms their consistency with the protocol administration at the primary research center. While studying accruals have been slow, we are currently tracking trends that explain reasons for screening failures to determine whether they can be addressed without undertaking protocol changes.

Section VI – Appendices

- A. DSMB Chair Letter
- B. IRB Continuing Approvals (UM/MSOM, Miami-VAMC, and Shepherd Center)
- C. DOD Trial Manual
- D. Lifestyle Balance Notebook
- E. Lifestyle Coaches Manual
- F. Two ASIA Abstracts
- G. Juried Manuscript

DEPARTMENT OF VETERANS AFFAIRS
VA BOSTON HEALTHCARE SYSTEM
1400 VFW Parkway SCI (128)
West Roxbury, MA 02132



In Reply Refer To:

October 18, 2011

Mark S. Nash, Ph.D., FACSM
Department of Neurological Surgery
The Miami Project to Cure Paralysis
University of Miami Miller School of Medicine
Lois Pope Life Center
1095 NW 14th Terrace, R-48
Miami, FL 33136

Re: SC090095 or W81XWH-10-1-1044, Obesity/Overweight in Persons with Early and Chronic SCI:
A Randomized Multi-Center Controlled Lifestyle Intervention

Dear Dr. Nash:

As DSMB Chair for the above-captioned award I have reviewed forwarded documents including the following:

1. Grant proposal, including narrative and all attachments
2. IRB documents from the three study sites
3. Trial manual
4. Lifestyle Balance Notebook
5. Lifestyle Coaches manual
6. Quarterly Report
7. Annual Report (draft)

Based upon my review and in accordance with responsibilities outlined in your narrative I authorize you and your colleagues to proceed with the trial pending final approval from the Program Officer, Human Research Protection Office (HRPO), Office of Research Protections (ORP) U.S. Army Medical Research & Materiel Command (USAMRMC). Going forward the DSMB will receive all IRB reports, information concerning (serious) adverse events, sponsor reports, and any proposed changes in the study procedures.

I wish you best success in conducting this important multi-site controlled trial, and with assistance from Drs. Myers and Keyser the DSMB will maintain oversight of all relevant study activities.

Sincerely,

A handwritten signature in dark ink, appearing to read "Sunil Sabharwal". The signature is fluid and cursive, with a large loop at the end.

Sunil Sabharwal, M.D.
Chief, SCI Service (128), VA Boston HCS
Assistant Professor of Physical Medicine and Rehabilitation
Harvard Medical School

cc: Jonathon Myers, Ph.D.
Randall Keyser, Ph.D.

Department of Veterans Affairs

Memorandum

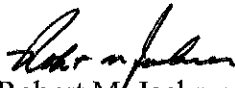
Date: December 7, 2012

From: Associate Chief of Staff for Research and Development (151/546)

Subj: Acknowledgment of Continuing Review Approval

To: Nash, Mark, Ph.D. (Protocol #5981.02)

1. The Associate Chief of Staff for Research has reviewed and concurs with the "Human Studies Subcommittee" decision regarding continuing review approval of your study entitled "Obesity/Overweight in Persons with Early and Chronic SCI".
2. If you have any questions, please contact the ACOS for Research at 305-575-3179.



Robert M. Jackson, M.D.

Human Studies Subcommittee (IRB)

Miami VA Healthcare System

1201 Northwest 16th St. • Miami, FL 33125-1693 • 305-575-3179 • Fax: 305-575-3126

IRB APPROVAL - Continuing Review

Date: December 10, 2012

From: Leonardo Tamariz, MD, MPH, Chairperson

Investigator: Mark Nash, Ph.D.

Protocol: Obesity/Overweight in Persons with Early and Chronic SCI

ID: 00889 Prom#: 0002 Protocol#: 5981.02

The following items were reviewed and approved at the 12/06/2012 meeting:

- Research Protocol (07/23/2010)
- Tracking Log for Reportable and Non-Reportable Eve (11/29/2012; Continuing Review 2012)
- Consent Form - Main Study Informed Consent (12/06/2012; Continuing Review 2012)
- Consent Form - Main Study Informed Consent (12/28/2011; Continuing Review)

REVISED - To reflect the addition of the following text to page 1 "NON-ACTIVE

- Report of Team Members - Updated_Report of Research Staff members (12/06/2012; Continuing Review 2012)

The following personnel are listed as staff members: M. Nash, Ph.D. and Alberto Martinez Arizala, M.D. The following individuals are listed as co-investigator however these individuals solely work at the University of Miami and conduct no research procedures at the Miami VA: T. Miller, Ph.D., M.D., A. Mendez, Ph.D., Luis Betancourt, P. Burns and G. Bigford.

- Continuing Review/Termination Form - Project is Active (12/06/2012; Continuing Review 2012)

This study is open to enrollment and no subjects have been enrolled to date.

- Financial Disclosure Form - COI_M. Nash (11/29/2012; Continuing Review 2012)
- Memo from Principal Investigator (12/06/2012; Continuing Review 2012)

In this letter, the PI provides a short summary as to why recruitment into the study has not occurred and provides a remediation plan on how to increase recruitment.

- Protocol History (11/29/2012; Continuing Review 2012)
- HIPAA Authorization Document (12/06/2012; Continuing Review 2012)
- HIPAA Authorization Document - HIPAA Authorization/Revocation Form (12/28/2011; Continuing Review)

REVISED - To reflect the addition of the following text to page 1 "NON-ACTIVE DUTY"

Approval is granted for a period of 12 months and will expire on 12/05/2013. Your Continuing Review is scheduled for 11/07/2013.

Approval by each of the following is required prior to study continuation (unless Exempt):

Human Studies Subcommittee (IRB)

Research & Development Committee

Approval for study continuation is contingent upon your compliance with the requirements of the Research Service for the conduct of studies involving human subjects.



Continuing Review for Protocol # 5981.02

Project/Program Title Obesity/Overweight in Persons with Early and Chronic SCIPrincipal Investigator Nash, Mark, Ph.D.VAMC Miami VAMC / 546Review Date: 12/06/2012

COMMITTEE FINDINGS:

1. The information given in the Informed Consent under the Description of Research by Investigator is complete, accurate, and understandable to a research subject or a surrogate who possesses standard reading and comprehension skills. ☒ YES ☐ NO
2. The informed consent is obtained by the principal investigator or a trained and supervised designate under suitable circumstances. ☒ YES ☐ NO
3. Every effort has been made to decrease risk to subject(s)? ☒ YES ☐ NO
4. The potential research benefits justify the risk to subject(s)? ☒ YES ☐ NO
5. If subject is incompetent and surrogate consent is obtained, have all of the following conditions been met; a) the research can't be done on competent subjects; b) there is no risk to the subject, or if risk exists the direct benefit to subject is substantially greater; c) if an incompetent subject resists, he will not have to participate; d) if there exists any question about the subject's competency, the basis for decision on competency has been fully described. ☒ YES ☐ NO
6. If the subject is paid the payment is reasonable and commensurate with the subject's contribution. ☒ YES ☐ NO ☐ NA
7. Members of minority groups and women have been included in the study population whenever possible and scientifically desirable. ☒ YES ☐ NO
8. Comments: (Indicate if Expedited Review) Continuing Review

This study is approved for 364 days from the review date indicated above.

☒ APPROVE☐ DISAPPROVE/REVISE

SIGNATURE OF CHAIRMAN

Leonardo Tamariz, M.D., Chairperson

DATE

IRB Approval: 12/06/2012

Expiration: 12/05/2013

MIAMI VAHCS
Human Studies Subcommittee

Request for Continued Approval of a Project Involving Human Subjects

Deadline for Submission: 12/6/2012

Principal Investigator: Nash, Mark, Ph.D.

Project Title: Overweight/Obesity in Persons with Early and Chronic SCI

Protocol # 5981.02

Funding/Administration: Department of Defense
Human Subjects

This Continuing Review covers the following Periodic Report of
Enrollment: From 12/28/11 to 12/28/12



RECEIVED
11/29/12

Checklist for Submission of a Request for Continuing Review

You are required to submit the following attachment:

1. Most recently approved informed consent document:
Yes ☒ No ☐ If, "no", please explain: N/A ☐ (This is a Retrospective Chart Review)
2. Most recently approved HIPAA Authorization/Revocation form:
Yes ☒ No ☐ If, "no", please explain: N/A ☐ (This is a Retrospective Chart Review)
3. Clean copy of the latest version of the informed consent document (not bearing the IRB approval stamp):
Yes ☒ No ☐ If, "no", please explain: N/A ☐ (This is a Retrospective Chart Review)
4. Clean copy of the latest version of the HIPAA Authorization/Revocation form (not bearing the approval stamp):
Yes ☒ No ☐ If, "no", please explain: N/A ☐ (This is a Retrospective Chart Review)
5. Provide the Tracking Log for Non-Reportable events:
Yes ☒ (Mandatory)
6. Provide current Disclosure of Available Funds and Financial or Non Financial Interests form (All Staff)
Yes ☒ (Mandatory)
7. Current version of the Report of Research Staff Members form:
Yes ☒ (Mandatory)
8. Have you and all your "research staff members" uploaded most current proofs of training on their SharePoint site:
Yes ☐ REMINDER: CITI/GCP has a two year expiration date.

NOTICE:

1. Periodic review of the human use component of all research projects is required within a time period previously determined by the IRB but not to exceed 12 months from the previous approval date.
2. FAILURE TO ACHIEVE SUBCOMMITTEE REVIEW AND APPROVAL PRIOR TO EXPIRATION OF THE CURRENT APPROVAL PERIOD WILL RESULT IN THE EXPIRATION OF APPROVAL TO CONDUCT THIS RESEARCH STUDY AT THIS MEDICAL CENTER.

If you have any questions regarding completion of these forms please contact Mitscher Gajardo at (305) 575-7241.

PROJECT STATUS

(These selections also apply to Retrospective Chart Review Study)

- ☒ Study is open to enrollment and no subjects have been enrolled to date
- ☐ Study is open to enrollment and subjects have been enrolled to date
- ☐ Study is open and patient medical records review is ongoing
- ☐ Closed to enrollment but subjects are still on the protocol regimen
- ☐ Closed to enrollment but follow-up of subjects continues
- ☐ Closed to enrollment or review of medical records is complete, but analysis of identifiable/coded data continues

PATIENT ACCRUAL / WITHDRAWAL AT MIAMI VAMC

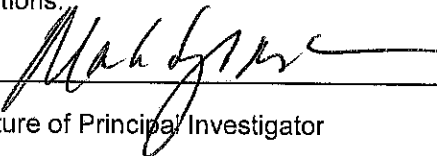
1. Total number of subjects (or chart reviews) approved for enrollment by the VAMC IRB: 0.
2. Total number of participants who were consented but not enrolled: 0.
3. Total number of subjects (or charts reviewed) enrolled since the initial approval: 0 Males: 0 Females: 0
4. Total number of subjects (or charts reviewed) enrolled since the last continuing review: 0 Males: 0 Females: 0
5. Are you the lead investigator of a multi-center research trial? ☒ Yes ☐ No
If "Yes" – Please state where (location of other institutions)? UM; Shepherd Center (Atlanta) If "No" – Skip to question #7
6. Indicate the number of participants enrolled since initial review at each site(s):

<u>4</u>	Males: <u>4</u>	Females: <u>0</u>
<u>3</u>	Males: <u>1</u>	Females: <u>2</u>
_____	Males: _____	Females: _____
7. Indicate whether SAE/AE and/or DSMB/DMC have been reported? ☐ Yes ☒ No
If "no", provide explanation: Participant enrolment and data collection is not ample enough to warrant a report.

INVESTIGATORS ACKNOWLEDGMENT OF RESPONSIBILITIES

Please read and sign the following:


I am aware that all research involving human subjects must receive prior approval by the Human Studies Subcommittee (IRB); that any changes in human use require prior approval by the Subcommittee; that a signed, initialed, and valid consent form must be obtained from each subject before entry into the study (when applicable); that CPRS progress notes are used to document all study visits; that continued human use requires periodic review as set by the IRB; that human use in projects without IRB approval must be discontinued; and that a copy of all consent forms and other related documents such as correspondence must be retained by the Principal Investigator for five (5) years after the study has terminated. This form, together with any requested additional information, is submitted in compliance with these regulations.




Signature of Principal Investigator

11/29/12

Date

 Approved / Disapproved



Signature of IRB Chair or Designee

IRB Approval: 12/06/2012^u
Continuing Review due by: 12/05/2013

IRB Approval Period Date



Title of Study: **Obesity/Overweight in Persons with Early and Chronic SCI: A Randomized Multi-Center Controlled Lifestyle Intervention**

Principal Investigator: **Mark S. Nash, Ph.D.**

Sponsor of Research Study: **DOD**

VAMC: **Miami / 546**

Version Date of IC: **December 6, 2012**

PURPOSE OF STUDY AND HOW LONG IT WILL LAST:

You are being asked to take part in a research study because you have a spinal cord injury resulting in paraplegia or tetraplegia, have been injured for more than one year, and are 18-65 years old. Your participation in this research study is voluntary.

The purpose of this research study is to determine whether exercise alone, or the combination of exercise and diet with professional support, will reduce body weight and decrease your risk for developing diabetes. It is known that people with spinal cord injury gain body weight after their injury, which makes daily activities more challenging to perform and increases the risk for medical conditions such as diabetes. A recent multicenter study conducted by the National Institutes of Health reported that the combination of diet, exercise, and professional support significantly reduced the risks for developing diabetes in a population of persons without disability. As similar combinations strategies have never been examined in people with spinal cord injury, this study will incorporate methods from the National Institutes of Health Diabetes Prevention Program (DPP) trial, and modify the exercise programs to fit the needs and capacities of people with spinal cord injuries. The study methods will then examine whether this 18 month program involving supervised and unsupervised treatment can lower body weight, reduce body fat, improve the outcomes of clinical tests that evaluate risk for diabetes, and enhance your quality of life.

This medical center will enroll 10 individuals from the Miami VA, currently in **NON-ACTIVE DUTY**, and a total of the 80 persons enrolled from 4 centers. Your participation in this study will last for 21 months and consist of 104 visits to Dr. Alberto Martinez-Arizala at the Miami VA and Dr. Mark Nash at the Applied Physiology Research Program of the Miami Project to Cure Paralysis at the University of Miami Medical Center.

DESCRIPTION OF THE STUDY INCLUDING PROCEDURES TO BE USED:

If you agree to be in this study, the following will happen to you:

Subject's Identification (I.D. plate, or give last-name, first, middle and include complete S.S.N.)

IRB Approval: 12/06/2012
Continuing Review due by: 12/05/2013



Title of Study: **Obesity/Overweight in Persons with Early and Chronic SCI: A Randomized Multi-Center Controlled Lifestyle Intervention**

Principal Investigator: **Mark S. Nash, Ph.D.**

Sponsor of Research Study: **DOD**

VAMC: **Miami / 546**

Version Date of IC: **December 6, 2012**

You will be enrolled in this study for approximately 21 months. During the initial 3 months you will be instructed to maintain your typical eating and activity habits. At the beginning of the 4th month you will be randomized (as by the flip of a coin) to one of two study groups. One study group (#1) will undergo exercise, a test diet, and an educational program taught by the study investigators. The other study group (#2) will undergo the same exercise program but maintain their usual diet. The study participants in this group will meet with the study investigators for the same amount of time as persons randomized to group #1, but not receive the same educational program. After 5 months of treatment you will work with a study coordinator to identify a type of exercise you would find appealing when continued in the home setting. Choices include resistance exercise (weight lifting) with elastic bands, Wii™ boxing, or other exercise you can perform at home. You will then perform the selected exercise in the laboratory for your last month of supervised exercise, which will allow the investigators to monitor your progress and make any suggestions for use of the equipment. At the end of the 6th study month you will continue the exercise at home for another 12 months. The following table shows what the investigators will be studying, and when. Each study activity and the time needed to accomplish it will be described. Treatments for group #1 (Exercise, Diet, and Behavior) and #2 (Exercise Only) will begin at study month 0. Thus, you will be studied for 3 months before treatments begin (-3 months).

Study Outcome /Activity	Sampling Time Points (By Study Month)									
	-3	0	1	2	3	4	5	6	12	18
Body Weight *	x	x	x	x	x	x	x	x	x	x
Body Composition		x						x		x
Dietary Habits	x							x	x	x
Fitness (Strength, Endurance * and Power)	x	x						x	x	x
Health-related Life Quality	x	x			x			x	x	x
Risk of Insulin Resistance and Diabetes *	x	x			x			x	x	X
Risk of Heart and Blood Vessel Disease *	x	x			x			x	x	X
Responses of blood fats and body metabolism to food intake	x	x						x		x

IRB Approval: 12/06/2012^u
Continuing Review due by: 12/05/2013



Title of Study: **Obesity/Overweight in Persons with Early and Chronic SCI: A Randomized Multi-Center Controlled Lifestyle Intervention**

Principal Investigator: **Mark S. Nash, Ph.D.**

Sponsor of Research Study: **DOD**

VAMC: **Miami / 546**

Version Date of IC: **December 6, 2012**

Assessments and Data Sampling

In addition to the described studies, we will quickly test your strength each month during months 1-6 using methods that are described below. We will test your strength in this way so that we can determine the resistance used during the exercise training sessions as you become stronger.

At the beginning of the study you will be teamed with a Lifestyle Coach, who will help you to modify your behaviors and assume a healthier lifestyle. The Lifestyle Coach may attend some of your training sessions, and might contact you if you need assistance. You may also call this individual if you are in need of additional support. All study participants will also be provided with a notebook, which will contain information about your personal level of fitness, body composition, and health risks. The investigators will take a picture of you, and using special software will show you what you will look like if you lose 7% of your body weight. These pictures will be mounted side-by-side in the notebook.

As part of the study you will be contacted every 1-2 weeks to see how you are managing your exercise and diet. Contacts will be made through a Viterion system, which is an electronic box that links with your regular telephone cord. The Telehealth software on the Viterion will ask you a series of questions, most of which can be answered as yes or no. You will simply answer these questions and the information will be transmitted to a Telehealth specialist. If you are not keeping up with your exercise or you need additional personal support, you will receive a call from your Lifestyle Coach, who will offer assistance and try to work through any study problems you may be experiencing.

PROCEDURES

Study Visits

During your initial visit to the Miami VA the investigators will ask you information about age, height, weight, date of injury, and injury level. The study physician will examine you and ensure that you are in good health, and that there are no reasons that you should not participate in the study.

If you are given clearance to participate by the study physician you will undergo a series of assessments. Table 1 identifies the study tests you will be undergoing during the 21 months of the study. All of the assessments will be performed 3 months before you begin exercise training. Some of these assessments are used to provide medical and study clearance, and are marked by an asterisk (*). Some assessments provide baseline data, and some are used for both assessment and data collection.

For example, if it is found during the initial exercise test that the exercise may pose a risk to your heart you may still be released for the study. The same is true if the resistance exercise causes pain, or the test of your sugar shows that you have diabetes. If you have a mild form of diabetes you may still be enrolled in the study,



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although if it doesn't improve by the time of the 3rd study month sampling, you may still be released from the study and referred for needed medical treatment of the condition.

During the first 3 study months you will keep your diet and exercise activities unchanged. Thereafter all study participants will undergo exercise conditioning and half the following diet and behavioral training sessions.

Exercise Training Sessions (1 hour, 3 times a week for 6 months [26 weeks])

During the first 3 study months you will keep your diet and exercise activities unchanged. Thereafter all study participants will undergo exercise conditioning and half the following diet and behavioral training sessions.

Exercise Training Sessions (1 hour, 3 times a week for 6 months [26 weeks])

The exercise training sessions performed in the clinic (initial 6 months) will each last 40-45 minutes and employ resistance training (weight lifting) and high-speed, low intensity endurance activities (arm cranking). You will perform 10 repetitions of lifting on each of the following exercise stations: (1) military press, (2) horizontal rows, (3) pectoralis ("pec") dec, (4) preacher curls (elbow flexion), (5) wide grip latissimus pull-down, and (6) seated dips. Every time you complete two resistance exercises you will perform arm exercise for two minutes on a stationary armcrank machine. You will rest 10 seconds between each set of repetitions, and will complete three cycles of the exercises. At the end of each month we will retest your strength and change the weight you lift to match your change in strength.

Behavior and Dietary Training Sessions (1 hour each, once weekly for 16 weeks) Study participants randomized to group #1 will participate in 16 educational sessions that will focus on behavioral control of your body weight. If you have someone who does your food shopping and cooking they are welcome to attend the sessions. The sessions will talk about ways to eat, changing your diet to one that is healthier, and what to do if you feel like overeating. The Diet being used for Group #1 will include lean meats and fish, healthy fruit and vegetables, and products with olives and olive oil. Important topics to be covered in these sessions will involve principles of energy balance between diet and exercise, methods to prevent unhealthy eating, and basic skills for eating and exercising when away from home.

Assessment Descriptions

Body Weight (Months -3, 0, 1, 2, 3, 4, 5, 6, 12, and 18 months: 10 minutes)

To measure your body weight you will wheel your wheelchair on a scale where you and the wheelchair will be weighed. You will then transfer to a therapy mat and the chair will be weighed without you. The difference between the two measurements is your body weight.



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Body Composition (Months -3, 0, 6, and 18 months: 30 minutes)

To measure the amount of muscle and fat your body contains you will undergo a dual x-ray absorptiometry scan. You will be assisted in a transfer to a machine, and will be asked to lie quietly while a series of low energy x-ray scans will be made from your head to toe. The scan will compute how much muscle and fat is contained in various parts of your body. The whole body scan will require about 10 minutes. You will be exposed to radiation this evaluation. The amount of radiation from the low energy x-ray scan of the whole body (DXA) is roughly equal to the amount of radiation experienced in one day's sunlight exposure

Dietary Habits (Months -3, 6, 12, and 18 months: 30 minutes)

After providing instructions on measuring and recording of foods you eat we will give you a food scale, measuring cup, pen, notebook, and an intake form to take home to write down what you eat for two days. After two days you will return the record for review, receive addition instructions if needed, and then write down what you eat for another two days, returning the notebook and materials to us at the end of the two days. The information you provide will be entered in a computer and analyzed for how many calories you eat and the nutrients in your food. If you are randomized to Group #1 you will be taught to change your diet. If you are randomized to group #2 you will keep eating like you always have.

Health Related Quality of Life (Months -3, 0, 3, 6, 12, and 18 months; 1 hour)

At six timepoints of the study you will be take three paper and pencil tests to see how you are feeling about life and your health. Some of the questions will ask you about your feelings about the relationship between your health and the quality of your life, some will ask you about how much support you need from those with which you come in contact and how you feel about that, and some will ask you if you have been sad, depressed and nervous.

Fitness Testing

You will undergo three types of fitness tests for endurance, power, and strength.

Endurance and Power Testing (Months -3, 0, 6, 12, and 18: 2 hours)

An arm exercise test will examine whether there are reasons that you should not undergo the exercise testing (such as risk of heart damage or unwanted responses to exercise) and determine your level of fitness. You will be prepared with electrode patches placed on your chest and stomach, and have a soft flexible mask placed over your nose and mouth. After preparation and instructions are completed you will position your wheelchair in front of an arm exercise machine and begin exercising at a low level. Every three minutes the resistance on the machine will increase making it harder to exercise. You will be instructed to work as hard and long as possible, but you can stop the test at any time. The investigators may stop the test at any time if they feel you have completed the test or your continued exercise may pose a hazard. After testing, the investigators will monitor your heart rhythm for 10 minutes and provide water and a towel.



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A separate arm exercise test will determine how much power you can create with your arms. After preparation and instructions are completed you will position your wheelchair in front of an arm exercise machine and begin exercising at a low level. After about a minute of warm up you will be instructed to pedal as fast as you can without any resistance. Within 3 seconds, your pedaling will be resisted by weights placed on the flywheel. You will continue to pedal as fast as you can for 30 seconds. After 30 seconds you will stop, the test will be over, and you will be provided water and a towel.

Strength Testing (Months -3, 0, 6, 12, and 18 months: 30 minutes)

To determine the resistance levels assigned for your exercise session the investigators will measure your maximum strength on a weight-lifting machine adapted for use by persons in a wheelchair. Testing will be performed using six weight-lifting maneuvers. The initial test for each station will be set at light weight. You will be instructed to perform eight repetitions of each maneuver at this weight, with each repetition lasting six seconds (3 seconds lifting, 3 seconds lowering). If eight repetitions are completed in controlled fashion the weight will be increased and the exercise repeated. You will continue to lift until you cannot complete 8 repetitions in a controlled manner using good lifting form.

Insulin Resistance and Risk of Heart and Blood Vessel Disease (Months -3, 0, 3, 6, 12, 18: 20 minutes)

To minimize the amount of blood we will take from you, the fasting blood sample for insulin, glucose (sugar), and lipids (fats, like cholesterol) will be measured on samples taken before you eat your meal. As there is no meal testing scheduled for months 3 and 12, we will instruct you to come to the Lois Pope Life Center in the fasted state and we'll take one sample of blood (15 ml = 3 teaspoons).

Responses of Blood Fats and Body Metabolism to Food Intake (Months -3, 0, 12, and 18: 20 minutes)

To test how your body digests a meal, you will arrive at the Lois Pope Life Center of the Miami Project on the first day of testing during the 8 – 10 day assessment period. You will restrict your intake of beverages containing alcohol and caffeine (such as cola and coffee) the day before fasting and fast overnight, but you will be allowed to drink water in the morning. To obtain blood samples a flexible plastic catheter (tube) will be placed in a vein near the surface of your forearm. A blood sample (3 teaspoons) will be drawn from the tube so that no additional need sticks of your arm will be needed. A soft flexible mask will be placed over your nose and mouth. The mask will collect air that you breathe out while you sit still for 15 minutes. Then, the mask will be removed and you will then be given a McDonald's breakfast meal consisting of an egg McMuffin, hash brown potatoes, and a small bottle of an orange soda that contains sugar. You will be allowed 15 minutes to consume the meal, after which the test will start. Blood samples (15 ml = 3 teaspoons each) will be taken at the start of the test, and at 30 minutes, 60 minutes (1 hour), 120 minutes (2 hours), 180 minutes (3 hours), and 240 minutes (4 hours) after eating the breakfast food. After the 240 minute (4 hour) sample you will be given a McDonald's lunch containing a Quarter Pounder with cheese, French fries, and a soda. Additional blood samples will then be taken at 300 minutes (5 hours), and 360 minutes (6 hours). In addition to the blood



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sampling, the soft flexible mask will again be placed over your nose and mouth at each of these time points (0, 30, 60, 120, 180, 240, 300, and 360 minutes). Between measurements you will be allowed to read, watch television, or nap, but will be asked to not exert yourself. You may not eat any other foods or snacks until the end of the test, but may drink plain water. You may bring any materials you wish to occupy yourself. At the conclusion of the test the catheter will be removed and pressure applied to stop any bleeding. The total amount of blood taken will be 24 teaspoons (120 ml), which is about one-quarter of a pint of blood. After your blood has been analyzed in the laboratory the leftover volumes will be destroyed.

DESCRIPTION OF ANY PROCEDURES THAT MAY RESULT IN DISCOMFORT OR INCONVENIENCE:

Taking part in this study may involve some added discomforts or inconveniences.

- 1) There may be mild discomfort in your arm or hand during the inserting of the catheter into the vein to obtain blood samples. You will be fasting overnight before the blood testing, and you may find the feelings of hunger discomforting.
- 2) You will be undergoing a series of assessments to test your strength, endurance, and power. It is likely that you will feel tired after the exercise sessions. During intense arm cranking exercise you may injure your hands, arms, or shoulders, which may make your daily activities more difficult to perform.
- 3) In rare cases the tape used to affix the EKG electrodes to your chest can cause an allergic reaction and some itching. This normally goes away within several hours after they are removed.

EXPECTED RISKS OF STUDY:

Taking part in this study may involve some added risks.

- 1) The risks of drawing blood or (giving drugs) through a vein are infection, bruising, slight pain, and uncommonly, fainting or the forming of a small blood clot at the site where the blood is drawn.
- 2) During endurance testing and the exercise session you will wear a flexible mask over your nose and mouth to collect the air you exhale, which will allow the investigators to measure how hard you are working. The mask placed over the mouth and nose may feel confining, although the air flowing through it will not be restricted in any way.
- 3) There is a risk of complications involving the heart. In exercise testing to exhaustion, 1 in 3000 persons sustains symptoms that require them to be seen by a physician or to be transported to a hospital. One in 30,000 persons sustains permanent heart damage or dies.



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4) You will be exposed to radiation when undergoing assessment of your body fat. The amount of radiation from the low energy x-ray scan of the whole body (DXA) is roughly equal to the amount of radiation experienced in one day's sunlight exposure.

5) In rare cases the tape used to affix the EKG electrodes to your chest can cause an allergic reaction. This normally goes away within several hours after they are removed.

6) Completing the questionnaires may make you feel nervous or upset.

7) If you know that you have a food allergy to eggs, red meat, milk products, wheat, or gluten you should not participate in this study. Consuming these foods may cause a skin rash or impede your ability to breath. If these symptoms should occur after consuming the McDonalds test meal it will be immediately reported, and will be cause for your release from the study.

In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the research staff.

You have the right to ask any questions about the potential and/or known hazards of this study at any time. You will be asked to tell the study doctor about any possible side effects you might have at any time during the procedures.

EXPECTED BENEFITS OF STUDY:

Anticipated Benefits to the Subject:

No benefit can be promised to you from being in this study, although it is likely that you will become more physically fit, and may possibly lose weight. You will be advised of your progress throughout the study, and will be provided the overall results of your participation and the entire study upon request at the completion of this study.

Anticipated Benefits to Society:

If successful in improving health and reducing body weight the study findings may:

- 1) Reduce health care costs and your need for assistance in the future.
- 2) Serve as a method for other persons with SCI to become more fit, healthy, and functional in their daily activities.
- 3) Serve as method for health and well-being for persons having other physical and emotional impairments.



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OTHER TREATMENTS AVAILABLE:

You do not have to take part in this study if you do not want to. If you do take part in this study, your doctors will treat your medical condition in the usual way. You can undergo exercise conditioning using commercially available equipment or accessible health clubs, and can restrict your intake of calories using one of many available diets. The diet we are using is a so-called 'Mediterranean diet' which you can do without enrolling in the study by obtaining information on the Internet or in a textbook.

COMPENSATION:

The VA will pay for required medical treatment for any study-related injury. An injury is considered study-related if it is caused by study activities that are different from the treatment you would have received if you were not in the study. The VA will not voluntarily pay medical treatment of other injuries or illnesses or any other type of compensation. You do not, however, give up your right to pursue this or other compensation by signing this consent or by being in the study.

PAYMENT FOR BEING IN THE STUDY:

You will be paid \$750 for your participation in the study. You must complete a W-9 form in order to receive payment for participation. This information will not be linked to any of the study data and will only be used for payment purposes. You will receive \$250 of the payment after completing the supervised clinical program (6 months), another \$250 after completing half of the extension program (another 6 months), and the balance after the study is completed (another 6 months). Payment will be made in the form of a check, which you should receive about 2-3 weeks after your paperwork is submitted for payment.

USE OF RESEARCH RESULTS:

Your name and other personal identifiable information will not be released to other parties not mentioned here unless you give us specific written permission to do so. You will be told and given in writing any new information that might affect your decision to be in the study. A photograph of you will be taken. A computer program will modify your picture to show you how you would look if you lost 7% of your body weight. VA form 10-3202 must be signed for us to take this picture, and will be attached to the consent.

You may ask any questions you want about the study and we will try to answer them.

CONFIDENTIALITY STATEMENT

Records identifying you may be inspected by the sponsor of this study, the study investigator and his personnel, or by one or more Federal governmental agencies for regulatory purposes. In addition, the Institutional Review Board (IRB) that approved this research may have access to this informed consent document as well as to your records for auditing purposes. The purpose of these audits is to help ensure that the research is being conducted in an appropriate manner and is in the public interest. Your name and other



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information identifying you will be protected to the fullest extent possible. It is possible that information shared with these groups could result in a loss of your privacy although employees of these groups are obligated to protect confidentiality. Any information shared with the sponsor may no longer be protected under federal law.

Participation and Withdrawal from the Study:

You may ask any questions you want about the study and we will answer them. You can refuse to be in the study or stop being in the study at any time. If you do refuse or stop, the care you are entitled to at the VA will not be affected in anyway.

You may contact the investigative team at the numbers listed on the last page of this consent document to report a research-related injury, for answers to your questions about the research or to voice concerns or complaints about the research.

If you have any questions about your rights or about medical care because of problems caused by being in the research study, you may call the Chief of Medical Administration Service or his representative at 305-575-7000, extension 3051. You can call either the patient Advocate's Office at (305) 575-3392 or the Institutional Review Board (IRB Office) at (305) 575-7000, extension 4465 to obtain answers to questions about the research; to voice concerns or complaints about the research; to obtain questions to questions about your rights as are search subject. You may also contact these numbers to verify that this is a valid study.

SPECIAL CIRCUMSTANCES:

The principal investigator can take you out of the study if for any reason he feels it is in your best interest to do so or if your being in the study must be stopped for administrative reasons. You will receive a copy of this document for your information. You may, if you want, show this document to family members, physicians or friends and ask their advice. None of the investigators or members of the research team have a financial conflict of interest. None of these persons or their families holds stock in a company or are paid by any of the sponsors.

Veterans will not be required to pay for medical care and services received as a part of a VA research program. If a veteran is receiving medical care and services from the VA that are not part of this study, and is a veteran described in federal regulations as a "category 7", they may be required to pay co-payments for the care and services that are not part of this study.

All research data collected in addition to protected health information will be destroyed in accordance with the record retention control schedule.



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Research Subjects Rights: I have read or have had read to me all of the above. Dr. _____ has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from the study at any time without penalty or loss of VA or other benefits to which I am entitled.

The results of this study may be published, but my records will not be revealed unless required by law.

In case there are medical problems or questions, I have been told I can call Dr. Nash at 305-243-3628 during the day and Dr. Martinez-Arizala at 305-807-7322 after hours. If any medical problems occur in connection with this study, the VA will provide emergency care.

I understand my rights as a research subject, and I voluntarily consent to participate in this study. I understand what the study is about and how and why it is being done. I will receive a signed copy of this consent form.

Subject's Signature or *Legally
Authorized Representative (LAR)

Date

Subject's Name or LAR (Print)

Signature of Person Obtaining Consent

Date

Person Obtaining Consent (Print)

*Only required if subject is not competent

IRB Approval: 12/06/2012
Continuing Review due by: 12/05/2013

**Miami VA Healthcare System
HIPAA Authorization
Release of Protected Health Information (PHI) for Research Purposes**

You have been asked to be part of a research study titled, "Obesity/Overweight in Persons with Early and Chronic SCI: A Randomized Multi-Center Controlled Lifestyle Intervention" under the direction of Dr. Mark Nash and his research team. The purpose of this study is to determine whether exercise alone, or the combination of exercise and diet with professional support, will reduce body weight and decrease your risk for developing diabetes in persons with people with spinal cord injury.

By signing this document, you authorize the Principal Investigator and his research team to collect the following data for research purposes .

- **Body Weight :** To measure your body weight you will wheel your wheelchair on a scale where you and the wheelchair will be weighed. You will then transfer to a therapy mat and the chair will be weighed without you. The difference between the two measurements is your body weight.
- **Body Composition :** To measure the amount of muscle and fat your body contains you will undergo a scan. You will be assisted in a transfer to a machine, and will be asked to lie quietly while a series of low energy x-ray scans will be made from your head to toe. The scan will calculate how much muscle and fat is contained in various parts of your body. The whole body scan will require about 10 minutes.
- **Dietary Habits :** After providing instructions on measuring and recording of foods you eat we will give you a food scale, measuring cup, pen, notebook, and an intake form to take home to write down what you eat for two days. After two days you will return the record for review, receive addition instructions if needed, and then write down what you eat for another two days, returning the notebook and materials to us at the end of the two days. The information you provide will be entered in a computer and analyzed for how many calories you eat and the nutrients in your food. If you are randomized to Group #1 you will be taught to change your diet. If you are randomized to group #2 you will keep eating like you always have.
- **Health Related Quality of Life :** At six timepoints of the study you will be take four paper and pencil tests to see how you are feeling about life and your health. Some of the questions will ask you about your feelings about the relationship between your health and the quality of your life, some will ask you about how much support you need from those with which you come in contact and how you feel about that, and some will ask you if you have been sad, depressed and nervous.

Fitness Testing: You will undergo three types of fitness tests for endurance, power, and strength.

- **Endurance and Power Testing :** An arm exercise test will examine whether there are reasons that you should not undergo the exercise testing (such as risks of heart damage or abnormal responses to exercise) and determine your level of fitness. You will be prepared with electrode patches placed on your chest and stomach, and have a soft flexible mask placed over your nose and mouth. The mask will collect air that you breath out during exercise and allow the Investigators to determine how hard you are working. After preparation and instructions are completed you will position your wheelchair in front of an arm exercise machine and begin exercising at a low level. Every three minutes the resistance on the machine will increase making it harder to exercise. You will be instructed to work as hard and long as possible, but can stop the test at any time. The Investigators will be monitoring the rhythm of your heart and breathing responses while you exercise, and may stop the test at any time if they feel you have completed the test or your continued exercise may pose a hazard. After testing the Investigators will monitor your heart rhythm for 10 minutes and provide water and a towel.
A separate arm exercise test will determine how much power you can create with your arms. After preparation and instructions are completed you will position your wheelchair in front of an arm exercise machine and begin exercising at a low level. After about a minute of warm up you will be instructed to pedal as fast as you can without any resistance. Within 3 seconds, your pedaling will be resisted by weights placed on the flywheel. You will continue to pedal as fast as you can for 30 seconds. After 30 seconds you will stop, the test will be over, and you will be provided water and a towel.

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- **Strength Testing:** To determine the resistance levels assigned for your exercise session the Investigators will measure your maximum strength on a weight-lifting machine adapted for use by persons in a wheelchair. Testing will be performed using six weight-lifting maneuvers: The initial test for each station will be set at light weight. You will be instructed to perform eight repetitions of each maneuver at this weight, with each repetition lasting six seconds (3 seconds lifting, 3 seconds lowering). If eight repetitions are completed in controlled fashion the weight will be increased and the exercise repeated. You will continue to lift until you cannot complete 8 repetitions in a controlled manner using good lifting form.
- **Insulin Resistance and Risk of Heart and Blood Vessel Disease:** To minimize the amount of blood we will take from you, the fasting blood sample for insulin, glucose (sugar), and lipids (fats, like cholesterol) will be measured on samples taken before you eat your meal. As there is no meal testing scheduled for months 3 and 12, we will instruct you to come to the Lois Pope Life Center in the fasted state and we'll take one sample of blood (15 ml = 3 teaspoons).
- **Responses of Blood Fats and Body Metabolism to Food Intake:** To test how your body digests a meal, you will arrive at the Lois Pope Life Center of the Miami Project on the first day of testing during the 8 – 10 day assessment period. You will restrict your intake of beverages containing alcohol and caffeine (such as cola and coffee) the day before fasting and fast overnight, but you will be allowed to drink water in the morning. To obtain blood samples a flexible plastic catheter (tube) will be placed in a vein near the surface of your forearm. A blood sample (3 teaspoons) will be drawn from the tube so that no additional needle sticks of your arm will be needed. A soft flexible mask will be placed over your nose and mouth. The mask will collect air that you breathe out while you sit still for 15 minutes. This allows the Investigators to determine how much energy your body uses while you are sitting still. Then, the mask will be removed and you will then be given a McDonald's breakfast meal consisting of an egg McMuffin, hash brown potatoes, and a small bottle of an orange soda that contains sugar. You will be allowed 15 minutes to consume the meal, after which the test will start. Blood samples (15 ml = 3 teaspoons each) will be taken at the start of the test, and at 30 minutes, 60 minutes (1 hour), 120 minutes (2 hours), 180 minutes (3 hours), and 240 minutes (4 hours) after eating the breakfast food. After the 240 minute (4 hour) sample you will be given a McDonald's lunch containing a Quarter Pounder with cheese, French fries, and a soda. Additional blood samples will then be taken at 300 minutes (5 hours), and 360 minutes (6 hours). In addition to the blood sampling, the soft flexible mask will again be placed over your nose and mouth at each of these time points (0, 30, 60, 120, 180, 240, 300, and 360 minutes) which will allow the Investigators to determine your metabolic responses to food intake. Between measurements you will be allowed to read, watch television, or nap, but will be asked to not exert yourself. You may not eat any other foods or snacks until the end of the test, but may drink plain water. You may bring any materials you wish to occupy yourself. At the conclusion of the test the catheter will be removed and pressure applied to stop any bleeding. The total amount of blood taken will be 24 teaspoons (120 ml), which is about one-quarter of a pint of blood. After your blood has been analyzed in the laboratory the leftover volumes will be destroyed.

Additionally, you will authorize your PHI to be released as a part of the study and at the request of the individuals listed below,

The University of Miami, Miller School of Medicine:


Mark Nash, Ph.D., Armando Mendez, Ph.D., Alberto Martinez-Azizala, MD., Tracie Miller, MD., Gregory Bigford Ph.D., Patricia Burns, MS, Luisa Betancourt MD. for subject screening and enrollment procedures, data collection and data analysis.

Shepherd Center, Atlanta:

Keith Tansey, M.D., Ph.D., (VAMA Atlanta), Deborah Backus, PT, Ph.D, Kathy Kreger for subject screening and enrollment procedures, data collection and data analysis

Yearly reports including data results will be reported to the Federal Funding Agency, the Department of Defense (DOD) and well as to the Institutional Review Board (IRB) at the University of Miami.

Any information shared with the sponsor may no longer be protected under federal law. We may share any information with others if required by law.

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If you properly execute this HIPAA authorization for disclosure of your protected health information (PHI) to an affiliate institution, transfer of the information to the affiliate server constitutes a "disclosure" under HIPAA, after which VA no longer owns the transferred information.

The VHA complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected.

This authorization will expire after 5 years of study completion.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you may sign and mail the attached Revocation of Authorization form to: Mark S. Nash, Ph.D., FACSM. 1095 NW 14th Terrace R-48, Miami, FL 33136. You can also ask a member of the research team to give you a form to revoke the authorization.

If you revoke this authorization, you will not be able to continue to participate in the research study. This will not affect the rights and benefits to which you are otherwise entitled.

If you revoke this authorization, researchers will continue to use information about you that has already been collected. Any information that has become part of this research study, prior to revocation, will not be removed or destroyed. No new information will be collected or added after you revoke the authorization.

If you do not sign this authorization, you will not participate in the study. Your treatment and benefits will not be affected in any way if you do not sign this authorization.

I have read and understand the information in this authorization form and have been given the opportunity to ask questions. If I have questions later, I understand I can contact Patricia Burns MS or Dr. Gregory Bigford. I will be given a signed copy of this authorization form for my records. I authorize the use of my identifiable information as described in this form.

Signature of Participant or Legally Authorized Power
of Attorney. (Attach copy of authority to sign if not Participant)

Date

Print Name of Person to Whom Authorization Pertains

Social Security Number

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Principal Investigator: **Mark S. Nash, Ph.D., FACSM**

Miami VA Healthcare System Revocation of Authorization Form

(Revocation of Authorization for Release of Protected Health Information for Research Purposes)

I hereby revoke my previous authorization for you to use or disclose my protected health information (PHI). This will discontinue my participation in the program.

I understand that the research team may continue to use and disclose PHI about me that has already been collected. However, they will use and disclose PHI only for the reasons discussed during the informed consent process when I joined the program. No new PHI will be collected or added after I revoke my authorization.

I understand that withdrawing from this program does not change my relationship with my healthcare providers, my future care, and will not in any way affect your access to healthcare or benefits.

I understand that this signed revocation can be mailed to the address below. I understand the VA will respond to this revocation in writing informing me that they have confirmed my request and the effective date of this revocation.

To revoke your authorization, you may sign and mail the attached Revocation of Authorization form to: Mark S. Nash, Ph.D., FACSM, 1095 NW 14th Terrace R-48, Miami, FL 33136

This revocation has been explained to me and I have been given the opportunity to ask questions. If I believe that my privacy rights have been compromised, I may contact the facility Privacy Officer to file a formal complaint.

Participants Signature

Date

Participants Name (Print)

Participant Date of Birth (MM/DD/YYYY) : _____

Participants Last 4 of SSN# : _____

12/06/2012 2012

UNIVERSITY OF MIAMI



University of Miami
Human Subjects Research Office (M809)
PO Box 016980, Miami, Florida 33101
1500 NW 12 Avenue, Suite 1002, Miami, Florida 33136

Ph: 305-243-3195
Fax: 305-243-3328
www.hsro.miami.edu

EXPEDITED – APPROVAL

June 20, 2012

Mark Nash, Ph.D.
University of Miami
Department of Neurological Surgery
Miami Project to Cure Paralysis
Medical Campus, Locator Code: R-48
Lois Pope Life Building , Room 1-48
Miami, FL 33136

HSRO STUDY NUMBER:	20100464
STUDY TITLE:	Obesity/Overweight in Persons with Early and Chronic SCI: A Randomized Multi-Center Controlled Lifestyle Intervention
IRB ACTION DATE:	6/18/2012
STUDY APPROVAL EXPIRES:	6/17/2013
Continuing Report #:	<u>CRR014030</u>
SPONSOR NAME:	Department of Defense
FWA #:	FWA00002247

On 6/18/2012, an IRB Chair approved the following items under the expedited review process. This review confirms that the grant application is consistent with the goals of the research proposed.

APPROVAL INCLUDES:

- Continuing Report (CRR014030)
- Research Materials (*English*)
 - Main Informed Consent Form

NOTE: Translations of IRB approved study documents, including informed consent documents, into languages other than English must be submitted to HSRO for approval prior to use.

A request to continue this study must be submitted to the HSRO at least **45 days** before IRB approval expires. If this study does not receive continuing IRB approval prior to expiration, all research activities must cease, and it may be officially suspended or terminated.

Sincerely,

[This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature]

Amanda Coltes-Rojas, MPH, CIP
Director
Regulatory Affairs & Educational Initiatives

/smh

cc: IRB File
Kimberly Anderson
Patricia Burns
Gregory Bigford
Mark Nash



Shepherd Center

2020 Peachtree Road, NW Atlanta, GA 30309-1465 404-352-2020 shepherd.org

Project #: 525
Event #: 183475-8

DATE: September 7, 2012

TO: *Kathy Kreger*

FROM: Jeffrey A. Lewis, Manager
Shepherd Center Research Review Committee

RE: Project # 525 - [183475-8] Obesity/Overweight in Persons with Early and Chronic
SCI: A Randomized Multi-Center Controlled Lifestyle Intervention

**Request for Project Continuation Approval with submission of Annual Status
Report on behalf of Deborah Backus, PT, PhD**

On behalf of the Shepherd Center Research Review Committee, this is to acknowledge receipt of a copy of your Annual Status Report dated September 7, 2012, submitted under cover of your letter dated September 7, 2012, which has been reviewed and approved, extending approval for the project through September 9, 2013.

Enclosed is the dated/stamped Informed Consent Form, approved for one additional year until September 9, 2013, which must be used for enrolling subjects into this protocol. One month before expiration you will be reminded to inform the RRC of the status of this project. Re-approval must be granted before the expiration date or the project will automatically be "suspended".

Failure to receive a notification that it is time to renew does not relieve you of your responsibility to provide the RRC with a request for "Continuation Approval" in time for the request to be processed and approved before your expiration date.

Changes in the research may not be initiated without RRC review and approval except where necessary to eliminate hazards to human subjects. Any changes, which have been necessary for the above reasons, must be promptly reported to the RRC.

The Principal Investigator must report to this office, in writing, within 10 days, any unanticipated problems involving risks to the subjects or others. Records pertaining to research must be retained for at least three years after completion of the research.

Sincerely,

A handwritten signature in blue ink, appearing to read 'JL', with a stylized loop and a horizontal stroke.

Jeff Lewis, IRB Manager

**OBESITY/OVERWEIGHT IN PERSONS WITH EARLY AND CHRONIC SCI:
A RANDOMIZED MULTI-CENTER CONTROLLED LIFESTYLE INTERVENTION.**

**PHASE IV MULTI-CENTER CLINICAL TRIAL
CLINICAL TRIAL MANUAL**

PRINCIPAL INVESTIGATOR:

Mark S. Nash, Ph.D., FACSM

Professor, Departments of Neurological Surgery and Rehabilitation Medicine

Principal Investigator, Applied Physiology Research Laboratory,

The Miami Project to Cure Paralysis

Director of Research, Rehabilitation Medicine

University of Miami Miller School of Medicine

Lois Pope Life Center, 1095 NW 14th Terrace, R48

Miami, FL 33136

Office: 305.243.3628

FAX: 305.243.3215

E-mail: msnash@miami.edu

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OVERVIEW

Obesity and endocrine-related diseases embodies a national health crisis and represents the sole chronic condition whose speed of growth and widespread dispersion resembles pandemics of communicable diseases. Data from the National Center for Health Statistics, Centers for Disease Control and Prevention (CDC) warns that 65.1% of Americans are currently overweight or obese, with a growth rate exceeding 10% in the past decade. Health risks posed by obesity are strongly associated with 15 co-morbid conditions including: cardiometabolic syndrome, hypertension, diabetes, coronary artery disease, congestive heart failure, stroke, osteoarthritis, sleep apnea, depression, cancer, respiratory failure, disorders of coagulation, and degenerative joint disease. More than 300,000 Americans die annually from obesity and endocrine-related illness, whose demographics cross all lines of gender, geographic region, socioeconomic status, race, heritage, and education level.

While obesity and an overweight body habitus among the general population is distressing, the prevalence of overweight among persons with disability is even more discouraging, where it has been reported that there is a 66% greater rate of obesity among people with disabilities than the general population. A recent regional study reported that extreme obesity (BMI ≥ 40) was four times more prevalent among persons with disability than those without. Additionally, statistical evidence on veterans with SCI reveal that 37% are overweight and another 31% obese.

Body weight gain through addition of fat is commonplace after SCI, and is likely caused by physical deconditioning, loss of metabolically active muscle mass, reduced whole body energy expenditure, restricted choices for exercise conditioning, and hypercaloric diet. Irrespective of cause, weight gain following SCI brings about diminished work capacity, musculoskeletal decline, pain, accelerated cardiovascular disease (CVD), worsening of neurological status, and progressive life dissatisfaction. It is also disturbingly co-morbid with dyslipidemia, glucose intolerance, and insulin resistance, has wide-ranging effects on health and function, and is far more difficult to manage and reverse than obesity occurring in persons without disability.

The current initiative addresses the societal concerns and disability priorities in a four-year randomized multi-center clinical trial examining 18 months of structured therapeutic lifestyle intervention (TLI) containing patient education, exercise, dietary intervention, and professional support in persons with chronic SCI. The study is modeled after widely reported successes of the Diabetes Prevention Program (DPP).

This clinical trial manual describes the overall study design and details regarding the key components of the study such that effective execution of study objectives, appropriate data collection and outcome measures can be obtained.

SUBJECT INFORMATION AND INCLUSION/EXCLUSION CRITERIA

Name:	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>
Code:	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>
D.O.B.	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>
Height:	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>
Weight:	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>

INCLUSION CRITERIA:			
Injury level	AIS A-C C5-L1	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>
Injury duration	> 1 year	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>
Age	18-65 years	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>
Gender	Male 80% Female 20%		<input type="checkbox"/>
Racial/Ethnic background	All		<input type="checkbox"/>
Population	Military and civilian constituents		<input type="checkbox"/>
BMI	≥ 20 kg/m ²	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>
Fasting dyslipidemia	HDL-C ≥ 40 mg/dL OR TG ≤ 150 mg/dL	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>
Impaired fasting glucose	≥ 100 mg/dL	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>

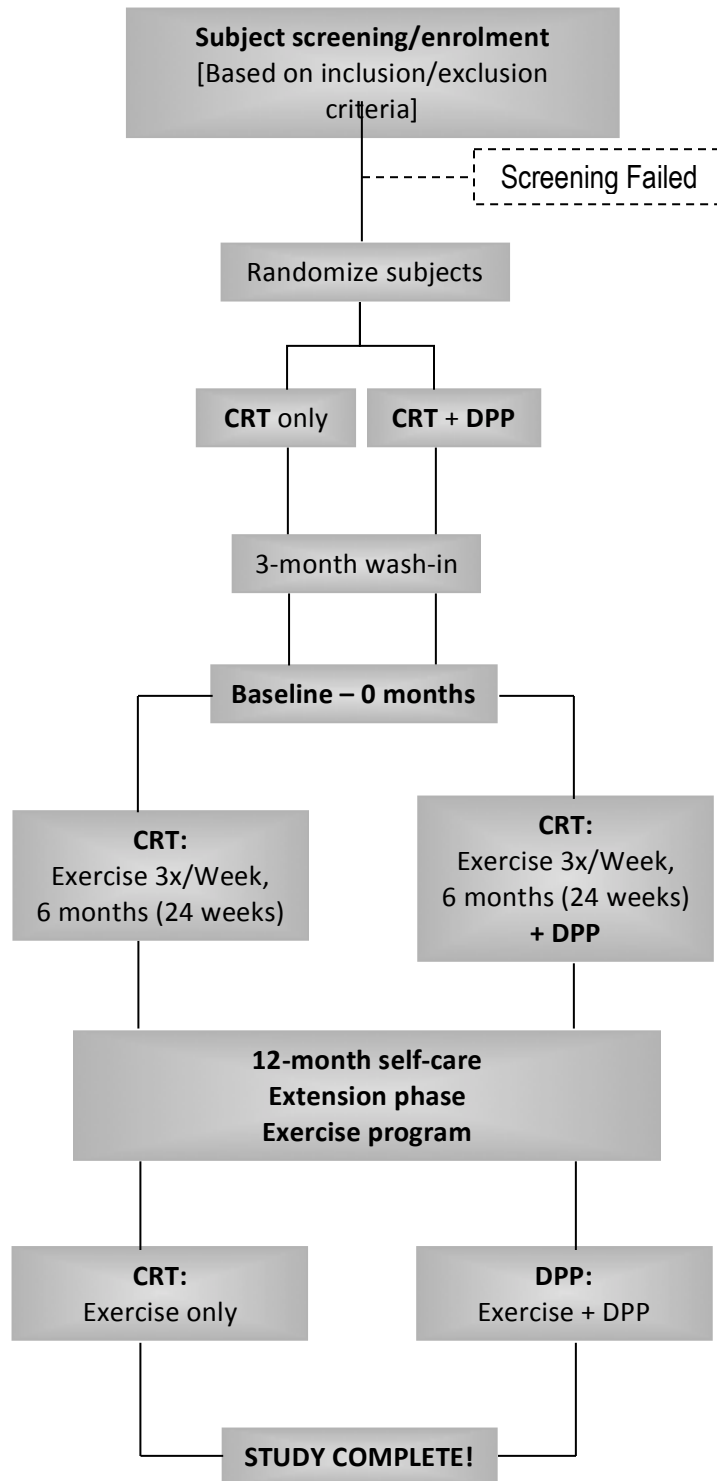
EXCLUSION CRITERIA:	
Structured exercise conditioning within 6 months of study entry	<input type="checkbox"/>
Defined diet involving caloric restriction or nutrient modification	<input type="checkbox"/>
Weight loss/gain of 5% within 6 months of study entry	<input type="checkbox"/>
Surgery within 6 months of study entry	<input type="checkbox"/>
Pressure ulcer within 3 months of study entry	<input type="checkbox"/>
Upper limb pain that limits exercise	<input type="checkbox"/>
Recurrent acute infection/illness requiring hospitalization of IV antibiotics	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Previous MI or cardiac surgery	<input type="checkbox"/>
6 month history of glucose-lowering and/or lipid-lowering drug therapy	<input type="checkbox"/>
Type I OR Type II diabetes	<input type="checkbox"/>
Daily intake of vitamin supplementation exceeding 100% RDA	<input type="checkbox"/>

Contraindicated disorder/condition: <ul style="list-style-type: none"> ▪ Traumatic brain injury – residual cognitive/behavioral impairment ▪ Substance abuse/dependence ▪ Psychiatric condition 		<input type="checkbox"/>		
Contraindicated drug therapy: <table border="0"> <tr> <td> <ul style="list-style-type: none"> ▪ β-adrenergic antagonists ▪ Maintenance α-blockers ▪ Methyl dopa ▪ Thiazide and loop diuretics ▪ Parasympatholytics </td> <td> <ul style="list-style-type: none"> ▪ Zinc ▪ Estrogen/hormone replacement therapy (excluding oral contraceptives) ▪ Insulin-sensitizing drugs ▪ Lipid-altering agents </td> </tr> </table>	<ul style="list-style-type: none"> ▪ β-adrenergic antagonists ▪ Maintenance α-blockers ▪ Methyl dopa ▪ Thiazide and loop diuretics ▪ Parasympatholytics 	<ul style="list-style-type: none"> ▪ Zinc ▪ Estrogen/hormone replacement therapy (excluding oral contraceptives) ▪ Insulin-sensitizing drugs ▪ Lipid-altering agents 		<input type="checkbox"/>
<ul style="list-style-type: none"> ▪ β-adrenergic antagonists ▪ Maintenance α-blockers ▪ Methyl dopa ▪ Thiazide and loop diuretics ▪ Parasympatholytics 	<ul style="list-style-type: none"> ▪ Zinc ▪ Estrogen/hormone replacement therapy (excluding oral contraceptives) ▪ Insulin-sensitizing drugs ▪ Lipid-altering agents 			
Fasting blood glucose ≥ 126 mg/dL after a fast of 8+ hours OR Symptoms of hyperglycemia and casual plasma glucose ≥ 200 mg/dL OR 2-hour plasma glucose \geq during an OGTT using a glucose load of 75g	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="checkbox"/>		

DESCRIPTION OF SPECIFIC AIMS AND HYPOTHESES

Specific Aim 1	<p>Reduce overweight/obesity and overweight/obesity-related health risks as assessed by the following primary study outcomes:</p> <ul style="list-style-type: none"> ▪ Body Weight ▪ Abdominal fat (subcutaneous + intra-abdominal) ▪ Insulin resistance ▪ Caloric intake in excess of expenditure
Hypotheses 1a-1d	<p>Persons with SCI who undergo 18 months of client-oriented education, exercise, diet, and support strategies of the DPP will experience to a significantly greater degree than participants randomized to exercise alone or a control:</p> <p><u>Hypothesis 1a</u>: Reduction of body mass <u>Hypothesis 1b</u>: Reduction of i) abdominal fat and ii) increase in whole body lean mass <u>Hypothesis 1c</u>: Reduced insulin resistance <u>Hypothesis 1d</u>: A significant difference will exist between caloric expenditure and intake in persons with SCI</p>
Specific Aim 2	<p>Improve attributes of fitness:</p> <ul style="list-style-type: none"> ▪ Endurance ▪ Strength ▪ Anaerobic Power
Hypotheses 2a-c	<p>Persons with SCI who undergo 18 months of client-oriented education, exercise, diet, and support strategies of the DPP will improve to a significantly greater degree than participants randomized to exercise alone or a control:</p> <p><u>Hypothesis 2a</u>: Endurance <u>Hypothesis 2b</u>: Strength <u>Hypothesis 2c</u>: Anaerobic power</p>
Specific Aim 3	<p>Reduce obesity-related health risks as assessed by the following secondary study outcomes:</p> <ul style="list-style-type: none"> ▪ Global fasting CVD risk ▪ Post-prandial lipemia ▪ Fasting and post-prandial whole body fat oxidation
Hypotheses 3a-c	<p>Persons with SCI who undergo 18 months of client-oriented education, exercise, diet, and support strategies of the DPP will experience to a significantly greater degree than participants randomized to exercise alone or a control:</p> <p><u>Hypothesis 3a</u>: Lowered TC:HDL ratio <u>Hypothesis 3b</u>: Decreased area under the TG response curve following a prandial challenge <u>Hypothesis 3c</u>: Increased levels of fasting and post-prandial whole body fat oxidation</p>
Specific Aim 4	<p>Improve self-perceived health and factors that modulate it</p>
Hypotheses 4a-e	<p>Persons with SCI who undergo 18 months of client-oriented education, exercise, diet, and support strategies of the DPP will experience to a significantly greater degree than participants randomized to exercise alone or a control:</p> <p><u>Hypothesis 4a</u>: Improved scores on a validated, population-sensitive instrument of HRQoL <u>Hypothesis 4b</u>: Improved scores on validated instruments that measure self-efficacy <u>Hypothesis 4c</u>: Improved scores on validated instruments that measure perceived social support <u>Hypothesis 4d</u>: Improved scores on validated instruments that measure depression <u>Hypothesis 4e</u>: Improved scores on validated instruments that measure anxiety</p>

OVERVIEW OF STUDY DESIGN AND TIMELINE OF DATA COLLECTION



Study outcome	Outcome sampling time points (by month)									
	-3	0	1	2	3	4	5	6	12	18
Body mass	▪	▪	▪	▪	▪	▪	▪	▪	▪	▪
DXA – body composition		▪						▪		▪
Insulin resistance	▪	▪			▪			▪	▪	▪
Caloric expenditure – intake	▪	▪						▪	▪	▪
Fitness attributes	▪	▪						▪	▪	▪
▪ VO_2^{Peak}										
□ TEE										
□ CH_2O oxidation										
□ Fat oxidation										
▪ 1 RM										
▪ $Power^{Peak}$										
▪ $Power^{Mean}$										
Global CVD risk	▪	▪			▪			▪	▪	▪
▪ TC:HDL										
▪ LDL:HDL										
▪ TG										
Post-prandial lipemia	▪	▪						▪		▪
▪ Δ TG response curve										
▪ Fat oxidation										
HRQoL	▪	▪			▪			▪	▪	▪

*These study outcome variables require blood sampling as outlined below:

Study outcome	Whole blood volume per time point	Outcome sampling time points (by month)					
		-3	0	3	6	12	18
Insulin resistance	2 ml Grey , 4 ml EDTA = 6 ml x 7 time points	▪	▪	▪	▪	▪	▪
Global CVD risk	2 ml Grey , 4 ml EDTA = 6 ml	▪	▪	▪	▪	▪	▪
Post-prandial lipemia (Δ TG response curve)	2 ml Grey , 4 ml EDTA = 6 ml x 6 time points	▪	▪		▪		▪
Total blood draw (ml)		84	84	48	84	48	84

SHIPMENT OF SPECIMENS.

General Instructions:

Carriers:

- ☐ We recommend shipping FedEx Priority Overnight service.
- ☐ Other carriers are acceptable providing they offer overnight delivery service.
- ☐ If choosing an alternate carrier, verify policies regarding dry ice shipments (UPS does not accept boxes for shipment with greater than 5 lbs of dry ice).

Shipping Time:

- ☐ Please ship samples on Monday, Tuesday, or Wednesday to avoid transit delays over a weekend.
- ☐ The biochemistry lab is closed on weekends.

Notify us:

- ☐ Prior to shipment, send notice of sample shipment via email to:
a.mendez@miami.edu
- ☐ Please include the following information:
Sample log (used to compare with actual sample received)
Shipment's tracking number

Shipping Address:

- ☐ Diabetes Research Institute Clinical Chemistry Lab
University of Miami Miller School of Medicine
Attention: Espy Perez
1450 NW 10th Ave
Miami, FL 33136
305.243.5314

Packing Instructions:

These recommendations follow the US Center for Disease Control (CDC) guidelines for transport of biological specimens within the United States (Postal Law 18 USC, 1716) and should be strictly followed.

☐ Supplies Needed:

- The shipping container should consist of a corrugated cardboard box with an insulating Styrofoam box insert (1-2" wall thickness). These containers are available from scientific supply companies such as VWR.
- Cryostorage storage boxes (cryovial size)
- Large Ziploc freezer bags (gallon size)
- Newspaper or other packing material
- Paper towels or other absorbent material
- Dry ice

☐ Packaging Serum/Plasma Samples:

- Individual sample tube should have clearly indicated sample id numbers labeled directly on the tube.
- Place cryovials (2 mL) into a 9 x 9 grid storage box (81 vials per box) into a 7" x 7" box.

Box size should be modified as needed if sample aliquots are in larger tubes.

- Cryostorage bags should be secured with rubber bands and place inside a large Ziploc freezer bag.
- Place a minimum of 5 lbs (2.5 kg) dry ice on the bottom of the shipping container. Larger boxes will require additional dry ice. A good rule of thumb is at least $\frac{1}{4}$ of the available space should be filled with dry ice.
- Place several layers of newspaper over the dry ice. This acts as a barrier and cushion between the dry ice and samples.
- Place samples (boxed and bagged) on top of newspaper. Fill any remaining space with additional packing material (crumpled paper, packing peanuts, etc.) to prevent shifting. Please remember that as the dry ice sublimates your samples may begin to shift. It is a good idea to loosely pack the container to the top. (Don't crack the Styrofoam box!)
- Place the sample log inside a Ziploc bag and lay this inside the box before you close the Styrofoam lid.
- Seal the outer cardboard box with packing tape. Shippers (FedEx, DHL) require you to affix a black and white dry ice label to the outside of the box. For FedEx, check YES in the "Dangerous Goods" box and write in the weight of the dry ice enclosed.

PROCEDURES AND INSTRUCTIONS FOR STUDY OUTCOME MEASURES

- a. **Body Mass** – Body mass, in Kg, will be measured on a calibrated scale that can accommodate the footprint of a wheelchair. Participants will be weighed both in and apart from their wheelchairs, with the outcome expressed as the average of two weightings.
- b. **DXA Body Composition** – Lean body mass will be determined by DXA as described in adults with paraplegia. Subjects will be instructed to wear comfortable clothing without metal clips. They will be assisted in transfer to the DXA scanner bed and placed in the supine position. Body composition measurements will be made in the anterior-posterior position using a Lunar DPX-L scanner generating X-rays at 2 energy levels (40 and 70 kVp). A series of transverse scans will be made from the head to toe at 2 mm intervals. Data will be collected over an area of 200 x 60 cm and expressed as grams of fat, grams of lean tissue mass, and/or percent lean body mass. Quality assurance measures should be undertaken daily and the scanner should be calibrated weekly using a density-gradient phantom. NOTE: Protection for bony prominences may be provided through use of a padded mat. The mat should be scanned separately to assure that it does not register scanned densities.
- c. **Insulin Resistance** – The assessment of whole-body insulin sensitivity will encompass both hepatic and peripheral tissues, which is derived by combining the insulin sensitivity index (ISI) during the oral glucose tolerance test (OGTT) with that obtained during the basal state, the latter of which primarily reflects hepatic insulin sensitivity. This composite 'whole-body ISI' during the OGTT [ISI (composite)] will be calculated as:

$$100^2 / [(FPG \times FPI) \times (G_{\text{MEAN}} \times I_{\text{MEAN}})]^{0.5}$$

where 100² represents a constant that generates values ranging from 1 to 12, FPG = fasting plasma glucose, FPI = fasting plasma insulin, and G_{MEAN} and I_{MEAN} reflect the 2-hour (75g) OGTT averages for glucose and insulin, respectively.

- d. **Caloric Intake – Expenditure** – Caloric intake will be monitored by using a 4-day food log, which includes weekend food consumption. An orientation session, typically lasting 1.5 hours, is to be completed with each participant. Participants will be provided a food scale, measuring cup, pen, notebook, and intake form. Both written and oral guidelines for weighing, measuring, and recording foods are to be reviewed during the orientation session. Participants are to be instructed to complete and return a sample 2-day dietary record to be reviewed and immediately returned. Food and drink consumption are then recorded for 2 additional days, and completed logs are to be returned to study personnel. Dietary intake and composition is analyzed using the nutritional software package Food Processor II Windows v. 7.6 (ESHA Research, Salem, OR).

Caloric expenditure will be calculated by indirect calorimetry:

$$\text{Kcal/min} = 4.92 (V) / [20.93 - \text{FEO}_2/100]$$

where the conversion factor of 4.92 kcals / liter of oxygen consumed is corrected for the fractional expired O₂ at rest and low intensity work. Food, ethanol, caffeine, and nicotine will be restricted for 8 hours before assessment, which is to be conducted at least 18 hours following moderate or

intense work. Measurement duration of 10 minutes with the first 5 minutes deleted and the remaining 5 minutes having a coefficient of variation <10% gives accurate readings of RMR.

- e. **Fitness Attributes** – Cardiopulmonary endurance, upper extremity dynamic strength and anaerobic power data measurements will be assessed.

Metabolic testing and analysis to assess cardiopulmonary endurance will be carried out by using an open-circuit indirect calorimetry system on a **Jaeger OxyCon Mobile** device.

- I. **VO_{2PEAK}** will be determined by a maximal continuous graded exercise test on an arm crank ergometer.

- An initial workload of 10W will be increased by 10W every 3 minutes until volitional exhaustion is reached for participants with paraplegia.
- An initial workload of 5W will be increased by 5W every 3 minutes until volitional exhaustion is reached for participants with tetraplegia – ACSM guidelines for exercise termination.

- Expired gases will be continuously analyzed via open-circuit indirect calorimetry, where

i. The rate of O₂ consumption – **VO₂** (L/min)

ii. The rate of CO₂ consumption – **VCO₂** (L/min)

iii. Respiratory Exchange Ratio – **RER** – will all be collected and utilized.

- Peak work will be defined as i) volitional exhaustion, ii) inability to maintain target workload, or iii) the point at which increasing workload fails to further increase VO₂.

- II. Total energy expenditure (**TEE**), whole body carbohydrate oxidation (**CH₂O**), and fat oxidation (**FO**) rates at rest and during exercise will be calculated from ventilator data collected using the following stoichiometric equations assuming negligible urinary nitrogen excretion rates:

- $TEE \text{ (kcal/min)} = 3.9VCO_2/RER + 1.11VCO_2$

- $CH_2O \text{ (g/min)} = 4.55VCO_2 - 3.219VO_2$

- $FO \text{ (g/min)} = 1.67VO_2 - 1.67VCO_2$

where rates of CH₂O and FO oxidation will be converted to weight relative units (μmol/kg·min) using the molecular weights of glucose (180 g/mol) and a representative TG (860 g/mol). Fat oxidation will be converted to fatty acid oxidation by multiplying by 3 (# mol fatty acids/mol TG).

One-repetition maximum (1RM) testing will be carried out to assess upper extremity dynamic strength as follows:

- Subjects will be instructed to perform 8 repetitions of each maneuver with each repetition lasting six seconds (3 seconds concentric, 3 seconds eccentric).
- If 8 repetitions are completed in a controlled fashion, weight will be increased and the exercise repeated – incremental increases will be 5 kg (paraplegia) and 2.5 kg (tetraplegia) until 8 repetitions **cannot** be completed.

- 1RM will be calculated using the Mayhew regression equation:

$$1RM = Wt / (0.533 + 0.419e^{-0.055 \cdot REPS})$$

where **1RM** is the calculated one repetition maximum strength, **Wt** is the resistance used in the last set where more than three repetitions but less than eight repetitions were completed, and **reps** equals the number of repetitions completed in the last set of testing.

- 1RM will be assessed in the following time schedule:

Exercise Maneuver	Upper extremity dynamic strength (1RM)									
	-3	0	1	2	3	4	5	6	12	18
Military press	▪	▪			▪			▪		
Horizontal rows	▪	▪			▪			▪		
Pec dec	▪	▪			▪			▪		
Preacher curls	▪	▪			▪			▪		
Latissimus pull-downs	▪	▪			▪			▪		
Seated dips ("Rickshaw")	▪	▪			▪			▪		

Anaerobic power will be determined via a standardized 30 second Wingate power test using a table-mounted arm crank ergometer as follows:

- Warm up will consist of a 5-minute non-resisted propulsion using the arm crank ergometer.
- Participants will then propel the non-resisted ergometer as fast as possible.
 - When cadence plateaus, a predetermined constant resistance is applied.
 - Participants continue propulsion for 30 seconds at maximal speed against the constant resistance.
 - Flywheel rate will be assessed by an electronic sensor.
- The resistance for each participant is set at:
 - 1.5-3% of body mass for tetraplegia.
 - 3.5% of body mass for paraplegia.
- Peak power** – the highest 5-second average mechanical power – will be measured and utilized.
- Mean power** – the average power of the 30-second test – will be measured and utilized.
- Global CVD Risk** – The primary assessment of global CVD risk will utilize the **TC:HDL ratio**, and secondary risk assessment will utilize the **LDL:HDL ratio**. Participants must abstain from caffeine

and alcohol consumption for 24 hours before testing, which will be conducted in the post-absorptive state following an overnight (10 hour) fast and 48 hours after the last exercise bout.

- 10 mL of whole blood will be drawn into citrate and Gel and Lysis Activator (serum) tubes between 8:00am-10:00am.
- Blood will be allowed to clot at room temperature for 30 minutes.
- Blood will be centrifuged at 1500 x g and the serum recovered.
- Platelet poor plasma will be prepared from citrate tubes by centrifuging at 3000 x g for 30 minutes
 - i. TG will be assayed
 - ii. HDL-C will be assayed after removal of apoB-containing lipoproteins by polyanion precipitation.
 - iii. LDL-C will be computed by the methods of Friedewald.

Global CVD risk will be measured as outlined in the time-course of data collection in section 1.

g. **Postprandial Lipemia** – The postprandial risk of lipemia will be determined using blood samples collected before and during the test meal administration.

- I. PPL will be calculated using values for TG concentration at all sampled points and will be plotted using graphing software (Graphpad) with the area under curve (AUC) measured by the software using the summed trapezoid method.
- Subjects will be prepared with a 21g Jelco Teflon catheter kept patent with sterile 0.9% saline.
- Blood samples will be taken at -15 min and 0 min, followed by ingestion of the test meal.
- Additional samples will be taken at 1, 2, 4, and 6 hours post-ingestion.

Postprandial Lipemia will be measured as outlined in the time-course of data collection in section 1.

- II. Rates of whole body fat oxidation will be determined at rest and following ingestion of a mixed-nutrient meal that is typical for persons with SCI.
- Subjects will rest comfortably in their wheelchair and will be fitted with a Hans-Rudolph Softmask.
- Expired gases will be collected and continuously analyzed for 30 minutes by open-circuit indirect calorimetry as described.
- Subjects will then ingest a PPL test meal.
- Following consumption, expired gases will again be analyzed during 15 minute periods evenly spaced over 180 minutes while subjects remain resting

- Subjects will be able to consume water ad libitum in between expired gas collection periods.
 - Energy expenditure values will be derived from respiratory data averaged during the last 10 minutes of each 15 minute expired gas collection period.
 - TEE, CH₂O and fat oxidation will be calculated as described.
- h. **HRQoL** – The medical Outcome Study Short Form (SF-36) will be used to test SCI participants on HRQoL, a multi-dimensional construct encompassing emotional, physical, and social domains that reflect an individual's subjective evaluation and reaction to a health condition.
- SF-36 will test 8 coalesced dimensions of health that create a physical component score (PCS) and a mental component score (MCS).
 - Site licenses in English and Spanish will be obtained for the SF-36 (v2, QualityMetric, Inc.) and is to be administered by an experienced investigator in the primary language of the participant.
 - Tests will be scored using the online service, and expressed as the coalesced scores for PCS and MCS.

Other psychosocial variables hypothesized to affect treatment adherence and HRQoL in exercise/weight-loss intervention will be measured.

- Self-efficacy will be measured with the Moorong Self-Efficacy Scale which has been validated for use in persons with SCI.
- Perceived social support will be measured by the Interpersonal Support Evaluation List (ISEL).
- Depression will be measured with the Beck Depression Inventory-II which has been validated for use in persons with SCI.
- Anxiety will be measured with the Spielberger State-Trait Anxiety Scale which has been validated for use in persons with SCI.

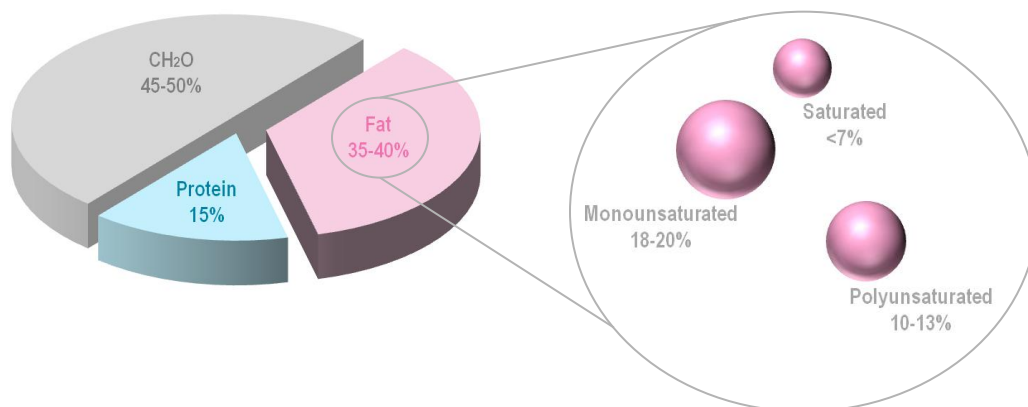
DIETARY INTERVENTION: CALORIC RESTRICTION AND THE MEDITERRANEAN-STYLE DIET

General Principles:

- Caloric restriction for SCI subjects will be **75%** of the RDA for persons without disability
- Sufficient to result in a weight loss of **1-2 lbs/week** and **~7%** of baseline body mass following 24-week intervention: **Consistent with DPP protocol.**
- Approximate target daily energy intakes prior to adjustment for physical activity are as follows:

Baseline weight (lbs)	Caloric intake (kcal/d)
120-170	1200
175-215	1500
220-245	1800
>250	2000

- Dietary intervention will follow the ***Mediterranean-style diets***, which recent evidence suggests may be optimal for weight loss and disease risk.
- Macronutrient composition of the Mediterranean-style diet is as follows:



THE TRADITIONAL HEALTHY MEDITERRANEAN DIET PYRAMID



- Example of serving breakdown of the major food groups in each weight defined calorie restricted group are as follows:

Caloric intake (kcal/d)	Food group (serving/day)					
	Fruit	Vegetable	Whole grain	Protein	Dairy	Oil
1200	2	2	3	2	1	4
1500	2	2	5	3.5	2	5
1800	2	3	6	4.5	2	7
2000	4	3	7	4.5	3	7

- A serving of each of the major food groups is as follows:

Fruit	1 serving = ½ cup OR 1 medium
Vegetables	1 serving = 1 cup leafy OR ½ cup raw/cooked
Whole grains	1 serving = 1 slice bread OR ½ cup rice/pasta/cereal
Protein-rich	1 serving = 1 oz OR ½ cup
Dairy	1 serving = 1 cup or 1½ oz cheese
Oil	1 serving = 1 tsp

FOOD INTAKE LOG – THE MEDITERRANEAN-STYLE DIET

S	M	T	W	Th	F	Sat
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

BREAKFAST		
Food Group	Food Item	Amount/Serving
Fruit		
Vegetable		
Dairy (low fat)		
Protein-rich food		
Whole grain		
Oil		

LUNCH		
Food Group	Food Item	Amount/Serving
Fruit		
Vegetable		
Dairy (low fat)		
Protein-rich food		
Whole grain		
Oil		

DINNER		
Food Group	Food Item	Amount/Serving
Fruit		
Vegetable		
Dairy (low fat)		
Protein-rich food		
Whole grain		
Oil		

SNACK		
Food Group	Food Item	Amount/Serving
Fruit		
Vegetable		
Dairy (low fat)		
Protein-rich food		
Whole grain		
Oil		

IMPORTANT POINTS TO REMEMBER

- **Mediterranean**-style diets emphasize the consumption of **fish**, **seafood**, and **poultry** over red meats and beef
- All **dairy** products should be **low-fat** or **fat-free**
 - ☐ Low-fat or fat-free milk, cheese, yogurt
- Use healthy alternatives when experiencing milk-related intolerance (stomach/digestion problems):
 - ☐ Lactose free low-fat or fat-free milk and cheese
 - ☐ Fortified soymilk, rice milk, or almond milk
- Only use **unsaturated** oils or products with **unsaturated** oils
 - ☐ Olive oil – use for adding taste, salad dressings, sauces, and cooking
 - ☐ Canola oil – use for cooking or frying
 - ☐ Margarine: Smart Balance and Promise brands, for example
- Remember, **eggs** are very high in protein! **Watch your intake** throughout the day when having eggs for breakfast.
- Avoid having eggs and shrimp, or other shellfish, on the same day to moderate cholesterol intake
- All juices should be 100% fruit juice with no *added* sugar
 - ☐ Orange juice should be **fortified** with calcium and other vitamins
- Limit other sugary beverages
 - ☐ Use diet beverages instead
- Choose **whole wheat** or **whole grain** products instead of white
 - ☐ Brown rice
 - ☐ Whole wheat breads
 - ☐ Whole wheat pastas
 - ☐ Pancakes and/or waffles
- Choose iron-enriched wholegrain cereals that are low in sugar (oatmeal, cream of wheat, bran flakes) to meet your iron needs.
- Snacks can be eaten during main meals (breakfast, lunch, dinner) as a dessert, for example, or eaten in-between meals as snacks
- Refer to your diet recipes for our Mediterranean approved Caesar dressing!

INTENSIVE DIETARY EDUCATION WILL BE A PART OF THE BEHAVIORAL AND LIFESTYLE TRAINING CURRICULUM AS DESCRIBED IN THE FOLLOWING SECTION

DIETARY DETAILS ARE AS FOLLOWS:

Specific Topics for Dietary Training Curriculum

<p>Session 3</p> <p>Healthy Eating</p>	<ol style="list-style-type: none">1. Learn about healthy eating by discussing the importance of using regular meal patterns and eating slowly.2. Introduce the My Plate from MyPlate.gov. Give tips on specific foods, healthy alternatives, and portions.3. Introduce all 5 food groups and show examples of foods within each group. <p>Activity- Rate Your Plate:</p> <ul style="list-style-type: none">• Participant will pick 4 meals from the previous week. They will fill in the plate per meal for each serving of food they had and what food group it came from.• Participant will answer questions on how their plate looked in comparison to My Plate Sample and if there were any healthier options they could've chosen. <ol style="list-style-type: none">4. Learn how to read a basic food label.<ol style="list-style-type: none">a. Go over serving size, servings per container, calories from fat, ingredient list and percent of daily values.b. Discuss limiting fat, cholesterol added sugar and sodium. <p>Activity: Give sample food label and have participants fill in correct answers from the label provided.</p> <ol style="list-style-type: none">5. To do next week they will:<ul style="list-style-type: none">• Keep track of weight• Fill out rate your plate forms everyday• Answer questions before next session.
<p>Session 4</p> <p>Get to know your Fats</p>	<ol style="list-style-type: none">1. Learn about Unsaturated Fat= <i>"The good guys"</i><ol style="list-style-type: none">a. Monounsaturated fatb. Polyunsaturated fat <p>Activity: Have participants write down 3 healthful fats they eat daily.</p> <ol style="list-style-type: none">2. Learn about Saturated Fat= <i>"The bad guys"</i><ol style="list-style-type: none">a. Saturated fatb. Trans fat

	<p>Activity: Have participants write down 3 harmful fats they eat daily then circle one to try to change for the following week.</p> <p>3. Learn how to read Fat on a food label</p> <ul style="list-style-type: none"> Teach what manufactures are required to list on the food label as to what manufactures are voluntarily allowed to list on food labels. <p>Activity: Give 2 sample food labels. Have participants fill in correct answers about fat from the label provided.</p> <p>4. To do next week</p> <ul style="list-style-type: none"> Keep track of the kinds of fat they eat everyday Write down everything they eat, drink and all daily activity Make a plan to change a habit and reach a goal Answer questions before next session.
<p>Session 7</p> <p>Tip the Calorie Balance</p>	<p>1. Learn about the two components of the calorie balance:</p> <ol style="list-style-type: none"> Calories consumed (food, beverages consumed) Calories expended (metabolic process and physical activity) <p>2. To reinforce the importance of maintaining a calorie balance in the weight loss process</p> <ol style="list-style-type: none"> Balancing food calories with activity calories <p>3. Learn how many calories it takes to lose/gain a pound</p> <p>4. Reinforce positive changes made so far</p> <ol style="list-style-type: none"> Changes to be more active Changes to eat fewer calories <p>5. Activity for next week:</p> <ol style="list-style-type: none"> Plan physical activities for the upcoming week Monitor calories consumed Reinforce portion control using portion size guide
<p>Session 10</p> <p>Four Keys to Eating Out</p>	<p>Learn strategies for a successful dining experience outside the home</p> <ol style="list-style-type: none"> Plan Ahead <ol style="list-style-type: none"> Steps to take charge of your eating out experience Ask for what you want <ol style="list-style-type: none"> Strategies to be firm and assertive
	<p>3. Take charge of what's around you</p> <p>4. Choose foods carefully</p> <ol style="list-style-type: none"> Healthy eating pitfall and success clue words <p>5. What's on the menu</p> <ol style="list-style-type: none"> Healthy restaurant menu options Fast food options <p>Activity – Describe a problem when you eat out:</p> <ul style="list-style-type: none"> Identify triggers and proactive solutions <p>6. To do next week</p> <ul style="list-style-type: none"> Continue to self-monitor weight, physical activity Critique action plan

Session 3: **Healthy Eating**

We'll begin today to keep track of your weight:

At every session, mark it on the How Am I Doing.

Your starting weight was _____ pounds.

Your weight today is _____ pounds.

Your goal weight is _____ pounds.

Write your weight down in one place. Keep a track book or your Journal.

Some parts of healthy eating include:

... the way you eat.

A regular pattern of meals is important.

A regular pattern will keep you from getting too hungry and losing control.

Eat slowly. If you eat slowly, you will:

- a) Digest your food better.
- b) Be more aware of what you're eating.
- c) Be more aware of when you're full.

Try pausing between bites. Put down your utensils. Enjoy the taste of your food!

Don't worry about cleaning your plate.

Serve yourself smaller portions to begin with.

... what you eat overall.

Let's start with the Food groups from My Plate.



Balancing Calories

- Enjoy your food, but eat less.
- Avoid oversized portions.

Foods to Increase

- Make half your plate fruits and vegetables.
- Make at least half your grains whole grains.
- Switch to fat-free or low-fat (1%) milk.
- Drink water instead of sugary drinks.

Tips for Foods:

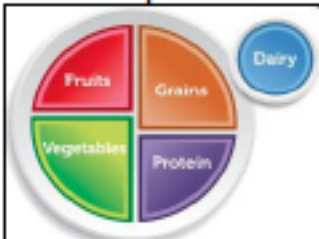
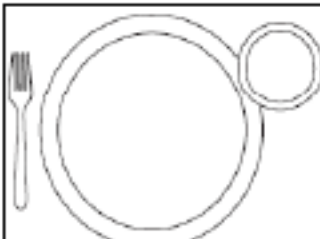
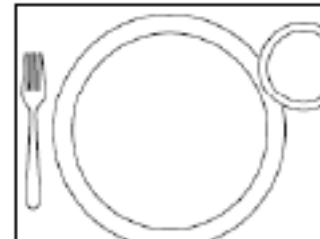
- Buy fresh fruits and vegetables in season. They cost less and are likely to be at their peak flavor.
- Buy packages of fruits or veggies for quick snacks.
- Include a green salad with your lunch and/or dinner every day.
- Try brown rice or whole-wheat pasta instead of white rice or pasta.
 - Check the ingredient list for the words "whole grain" or "whole wheat" to decide if they are made from a whole grain. (Some foods are made from a mixture of whole and refined grains).
- Buy the leanest meat cuts and lean ground meats such as boneless skinless chicken breasts and turkey cutlets.
 - Choose lean or low-fat luncheon meats for sandwiches instead of luncheon/deli meats with more fat, such as regular bologna or salami.
 - Trim away all of the visible fat from meats and poultry before cooking.
 - Drain off any fat that appears during cooking.

<p style="text-align: center;">Vegetable Group</p> <p>Vegetables may be raw or cooked; fresh, frozen, canned. Any vegetable or 100% vegetable juice counts as a member of the Vegetable Group.</p>	<p>Lettuce, spinach, broccoli, carrots, peppers, green beans, cauliflower, celery, cucumbers, Plantains, mushrooms, zucchini, onions, potatoes, and corn. Some Juices like tomato juice or V-8.</p>
<p style="text-align: center;">Grain Group</p> <p>Any food made from wheat, rice, oats, or other cereal grain is a grain product.</p> <p>Grains are divided into 2 subgroups: Whole grains Refined grains.</p>	<p>Whole grains: brown rice, oatmeal, popcorn, wheat tortillas, wild rice, whole wheat bread and breakfast cereals like whole wheat cereal flakes</p> <p>Refined grains: white bread, corn & flour tortillas, couscous, crackers, grits, white noodles and pastas, pitas, pretzels and Breakfast cereals like corn flakes.</p>
<p style="text-align: center;">Fruit Group</p> <p>Fruits may be fresh, canned, frozen, or dried, and may be whole, cut-up, or pureed.</p> <p>Any fruit or 100% fruit juice counts as part of the Fruit Group.</p>	<p>Apples, apricots, bananas, berries, grapes, kiwi fruit, lemons, limes, mangoes, melons, oranges, peaches, pears, papaya, pineapple plums, prunes, and raisins.</p> <p>100% Fruit juices like orange, apple, grape, and grapefruit.</p>
<p style="text-align: center;">Milk Group</p> <p>All fluid milk products and many foods made from milk are considered part of this food group.</p> <p>Most Dairy Group choices should be fat-free or low-fat. Foods made from milk that retain their calcium content are part of the group.</p>	<p>Milk: fat-free (skim), low fat (1%), reduced fat (2%), whole milk, lactose-reduced or lactose free milks Cheese: cheddar, mozzarella, Swiss, parmesan, ricotta, cottage, American Yogurt: fat-free, low fat, reduced fat, whole milk yogurt Milk-based desserts: puddings, ice milk, frozen yogurt, ice cream</p>
<p style="text-align: center;">Protein Group</p> <p>All foods made from meat, poultry, seafood, beans and peas, eggs, processed soy products, nuts, and seeds are considered part of the Protein Foods Group. Beans and peas are also part of the protein group.</p>	<p>Meats, game meats, lean luncheon or deli meats, organ meats, poultry, and eggs. beans and peas: soy beans, split peas, tofu (bean curd made from soybeans), veggie burgers, texturized vegetable protein (TVP), nuts and seeds, seafood</p>
<p>Remember: The amount of each group you need to eat depends on your age, sex, and how physically active you are!</p>	

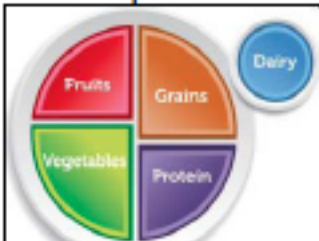
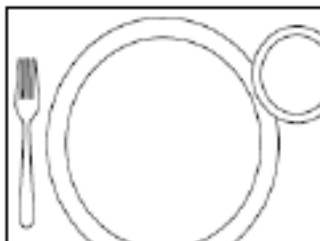

Rate Your Plate (Y)

1. Pick four meals from last week's Keeping Track. Fill in the dates.
2. Fill in each plate for every serving you ate from each food group. The plate beside shows you the minimum number of servings recommended.

Date: ____/____/____

Sample	Lunch	Dinner
		

Date: ____/____/____

Sample	Lunch	Dinner
		

What could *you* do to better to match My Plate?

Are there healthier options to any foods that you ate? If so, what are they?

Learning how to Read a Food Label

Become a smart shopper by reading food labels to find out more about the foods you eat. The Nutrition Facts panel found on most food labels will help you:

Nutrition Facts	
Serving Size 1 slice (51g) Servings Per Container 6	
Amount Per Serving	
Calories 110	Calories from Fat 90
	% Daily Value*
Total Fat 11g	15%
Saturated Fat 2.5g	11%
Trans Fat 2g	
Cholesterol 0mg	0%
Sodium 300mg	12%
Total Carb 15g	5%
Dietary Fiber less than 1g	2%
Sugars 1g	
Protein 3g	
Vitamin A 20%	Vitamin C 4%
Calcium 45%	Iron 0%
Thiamin 8%	Riboflavin 6%
Niacin 6%	

*Percent Daily Values are based on a diet of other people's misdeeds.

• Find out which foods are good sources of fiber, calcium, iron, and vitamin C

• Compare similar foods to find out which one is lower in fat and calories

• Search for low-sodium and low sugar foods

• Look for foods that are low in saturated fat and trans fats

Serving Size & Servings per Container or Package

• Look here for both the serving size (the amount for one serving), and the number of servings in the package.

• Remember to check your portion size to the serving size listed on the label. If the label serving size is one cup, and you eat two cups, you are getting twice the calories, fat and other nutrients listed on the label.

Calories and Calories from Fat

Find out how many calories are in a single serving and the number of calories from fat. It's smart to cut back on calories and fat if you are watching your weight!

Let the Percent Daily Values Be Your Guide

Daily Values (DV) are average levels of nutrients for a person eating 2,000 calories a day. A food item with a 5% DV means 5% of the amount of fat that a person consuming 2,000 calories a day would eat.

- 5 percent or less is low — try to aim low in total fat, saturated fat, cholesterol, and sodium
- 20 percent or more is high — try to aim high in vitamins, minerals and fiber

Ingredients are listed in order so you get an idea of how much of each ingredient is in the food. When something is listed first, second, or third, you know that this food probably contains a lot of it.

Tips on Food Labels:

Limit Fat, Cholesterol and Sodium:

Eating less of these nutrients may help reduce your risk for heart disease, high blood pressure and cancer:


- Total fat includes saturated, polyunsaturated and monounsaturated fat. Limit to 100% DV or less per day.
- Saturated fat and trans fat are linked to an increased risk of heart disease.
- Sodium — high levels can add up to high blood pressure. Try to stay below 1500 mg per day, and NO higher than 2300 mg per day!

Additional Nutrients

Carbohydrates — there are three types of carbohydrates: sugars, starches and fiber. Select whole-grain breads, cereals, rice and pasta plus fruits and vegetables.

Sugars — simple carbohydrates or sugars occur naturally in foods such as fruit juice (fructose), or come from refined sources such as table sugar (sucrose) or corn syrup.

Now that you know a little more about food labels, you can read up on what you're eating!



Ingredients: Dehydrated Potatoes, Modified Food Starch, Corn Oil, Sugar, Salt, Soy Lecithin, Leavening (Monocalcium Phosphate and Sodium Bicarbonate), and Dextrose.
No Preservatives.

Nutrition Facts	
Serving Size 1 oz. (28g) About 10 chips	
Servings Per Container 10	
Amount Per Serving	
Calories 120	Calories from Fat 30
% Daily Value*	
Total Fat 3g	6%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 200mg	8%
Total Carbohydrate 21g	7%
Dietary Fiber 3g	6%
Sugars 2g	
Protein 2g	
Vitamin A 0%	Vitamin C 6%
Calcium 4%	Iron 0%
Thiamin 4%	Niacin 6%
Vitamin B6 4%	Phosphorus 6%
Zinc 2%	

*Percent Daily Values are based on a diet of other people's secrets. Your daily values may be higher or lower depending on your calorie needs.

	Calories: 120	2,000	2,500
Total Fat	Less than 65g	65g	80g
Sat Fat	Less than 25g	25g	35g
Cholesterol	Less than 300mg	300mg	300mg
Sodium	Less than 2,400mg	2,400mg	2,400mg
Total Carbohydrate	30g	30g	35g
Dietary Fiber	25g	25g	35g

*Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Let's try this label:

What is a serving of this item? _____

How many servings are there? _____

How many calories are for one serving? _____

How many calories would you eat if you ate 3 servings? _____

Is this a lot for one food item? _____
(Yes! We will explain in a later session)

How much sodium would you get if you ate 3 servings of this item? _____

Is this a lot for one food item? _____

What ingredient does this product have the most of? _____

To do next week:

I will:

- ☐ Keep track of my weight and what I eat.
- ☐ Fill out the Rate Your Plate form every day.
- ☐ Answer these questions before our next session:

Did you make any changes during the week to better match My Plate?

If yes, what were they?

What problems did you have? How did you solve them?

For next week:

Keep track of my food groups by filling in my plate.
Fill in the day of the week. For the meal place B- for breakfast, L- for lunch, or D for Dinner.



Day _____ Meal _____



Day _____ Meal _____



Day _____ Meal _____



Day _____ Meal _____



Day _____ Meal _____



Day _____ Meal _____



Day _____ Meal _____



Day _____ Meal _____



Day _____ Meal _____



Day _____ Meal _____



Day _____ Meal _____



Day _____ Meal _____



Session 4: Get to know your Fats

Fats, or lipids, are nutrients in food that the body uses to build nerve tissue (like the brain) and hormones. Fats and oils are important parts of a healthy diet, but the type of fat you choose can make a big difference for the health of your heart. By understanding how fats work in the body, knowing the difference between the good guys (unsaturated fat) and the bad guys (saturated fat), you can eliminate excess fat from your diet and eat better for your health.

Two Types of Healthy Fat: “The Good Guys”

- **Monounsaturated fat.** This is a type of fat found in a variety of foods and oils. Studies show that eating foods rich in monounsaturated fats (MUFAs) improves blood cholesterol levels, which can decrease your risk of heart disease. Research also shows that MUFAs may benefit insulin levels and blood sugar control, which can be especially helpful if you have type 2 diabetes.

Foods that are rich in Monounsaturated fat are:

- avocado
- canola oil · olives and olive oil · cashews and cashew butter · sesame seeds
- almonds and almond butter · peanuts, peanut butter and peanut oil



- **Polyunsaturated fat.** This is a type of fat found mostly in plant-based foods and oils. Evidence shows that eating foods rich in polyunsaturated fats (PUFAs) improves blood cholesterol levels, which can decrease your risk of heart disease. PUFAs may also help decrease the risk of type 2 diabetes. One type of polyunsaturated fat, omega-3 fatty acids, may be especially beneficial to your heart. Omega-3s, found in some types of fatty fish, appear to decrease the risk of heart disease. They may also protect against irregular heartbeats and help lower blood pressure levels.

Foods that are rich in Polyunsaturated fat are:

- some salad dressings · walnuts
- corn oil · sunflower oil · some tubs of margarine · pumpkin and sunflower seeds

Name 3 kinds of healthful fats you eat? (Unsaturated)

1. _____
2. _____
3. _____

Two Types of Harmful Fat: “The Bad Guys”

- **Saturated fat.** This is a type of fat that comes mainly from animal sources of food. Saturated fat raises total blood cholesterol levels and low-density lipoprotein (LDL) or “bad” cholesterol levels, which can increase your risk of cardiovascular disease. Saturated fat may also increase your risk of type 2 diabetes.

Foods that are high in saturated fat are:

- skin from chicken and turkey · lard · butter · chocolate
- high fat dairy products such as cream, whole milk, cheese, regular ice cream and sour cream
- high-fat processed meats like ground beef, bologna, hot dogs, sausage, bacon, and spareribs

- **Trans fat.** Most trans fats are made during food processing through heating up of unsaturated fats. Some occur naturally in foods, especially foods from animals. These trans fats are “chemically-altered fats” (companies use them to increase the shelf life of their products).

- Research studies show that trans fat can increase “bad” cholesterol (LDL) and lower the healthy “good” cholesterol (HDL). This can increase your risk of heart disease.

Foods that are high in trans fat are:

- processed foods like crackers, snacks, breads, chips, and baked goods
- candy like caramels and chocolates · shortening like Crisco
- some fast foods such as French fries and biscuits · dips



Most of the fat we eat (70% of it) is hidden in foods.

Let's uncover it! Here's a lunch menu:

Fried fish sandwich	5 teaspoons of fat
Large French fries	6 teaspoons of fat
Apple turnover, fried	4 teaspoons of fat
Milkshake, with ice cream	5 teaspoons of fat
Total:	20 teaspoons of fat (That's about 1 entire stick of butter or margarine!)

To help you stay on your weight goal, we'll help you eat healthy.

Make a plan to eat less harmful fat and follow it.

Write down 3 foods you eat that are high in Saturated or Trans fat. Circle one.

1. _____
2. _____
3. _____

Now, what is one way you can cut your saturated fat intake for next week? (There are examples below) Be sure it is something you can do!

1. _____

<i>Instead of...</i>		<i>Replace with...</i>
Bologna, beef or pork, 1 ounce	→ Lower the fat in meats.	Turkey breast, 1 ounce
American cheese, 1 ounce	→ Use low-fat substitutes.	American cheese, low-fat, 1 ounce
Potato chips, 1-ounce bag	→ Eat smaller amounts.	Potato chips, ½ of a 1-ounce bag
Fish, flounder, deep fried, 3 oz	→ Cook in healthy ways.	Fish, flounder, baked, 3 oz.
Mashed potatoes, ½ cup, whole milk and butter	→ Use low-fat flavorings and substitutes.	Mashed potatoes, ½ c, skim milk, and margarine
Green beans, w/bacon, ½ cup	→ Use low-fat flavorings.	Green beans, steamed, ½ cup
Ice cream, premium, ½ cup of ice cream [for a rare treat.]	→ Eat less often.	Frozen yogurt or sherbet ice cream
Regular margarine or butter	→ Eat light option.	Light-spread margarines, or diet margarine
Chicken Nuggets	→ Cook in healthy ways.	Chicken breast, broil, or grill, 3 oz

Now that you know how to read a food label... what does “Total Fat” mean?

Nutrition Facts		
Serving Size	4 cookies (30g)	
Servings Per Container	4	
Amount Per Serving		
Calories 220	Calories from Fat 110	
	% Daily Value*	
Total Fat 12g	18%	
Saturated Fat 6g	30%	
Trans Fat 0.5g		
Cholesterol 10mg	2%	
Sodium 70mg	4%	
Total Carbohydrates 25g	8%	
Dietary Fiber 1g	4%	
Sugars 20g		
Protein 3g		
Vitamin A 0%	• Vitamin C 8%	
Calcium 2%	• Iron 4%	
* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.		
	Calories:	2,000 2,500
Total Fat	Less than 65g	80g
Sat Fat	Less than 20g	25g
Cholesterol	Less than 300mg	300mg
Sodium	Less than 2,400mg	2,400mg
Total Carbohydrate	300g	375g
Dietary Fiber	25g	30g
Calories per gram		
Fat 9 • Carbohydrates 4 • Protein 4		

Total Fat on the food label represents the amount of fat in one serving of the product.

Remember Total Fat comes from four sources:

- Monounsaturated Fat > Good Guys
- Polyunsaturated Fat > Good Guys
- Saturated Fat > Bad Guys
- Trans Fat > Bad Guys

Note: Manufacturers are *required* to list saturated fat and trans fat as subcategories of total fat and can *voluntarily* list monounsaturated fat and polyunsaturated fat.

There are 12 grams of total fat in one serving of this product

6 grams = saturated fat & 0.5 grams = trans fat.

You can assume the remaining 5.5 grams of fat come from monounsaturated and/or polyunsaturated fat, even though it's not listed on the label.

Question: What if you eat a larger serving than is listed on the label?

Answer: You will be eating more fat (grams) than is listed on the label!!

Read this Food Label:

Nutrition Facts

Serving Size 1 oz. (28g/about 21 pieces)

Servings Per Container 10

Amount Per Serving

Calories 150

Calories from Fat 80

% Daily Value*

Total Fat	9 g	14%
Saturated Fat	2g	10%
Cholesterol	0mg	0%
Sodium	300mg	12%
Total Carbohydrate	16 g	5%
Dietary Fiber	less than 1g	1%
Sugars	less than 1 g	
Protein	2g	

Vitamin A	0%	Vitamin C	0%
Calcium	0%	Iron	2%

* Percent Daily Values are based on a 2,000 Calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Nutrition Facts

Serving Size 1 cup (228g)

Servings Per Container 2

Amount Per Serving

Calories 280

Calories from Fat 110

% Daily Value*

Total Fat	12g	18%
Saturated Fat	3g	15%
Trans Fat	1.5g	
Cholesterol	30mg	10%
Sodium	470mg	20%
Total Carbohydrate	31g	10%
Dietary Fiber	0g	0%
Sugars	5g	
Protein	5g	

Vitamin A	4%
Vitamin C	2%
Calcium	20%
Iron	4%

*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calorie:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

☐ Look at the Serving size

☐ Look at the Total Fat in grams:

How much is Saturated Fat _____g

How much is Trans Fat _____g

How much Polyunsaturated and Monounsaturated Fat _____g

Let's Try Another Label:

What is the Serving size? _____

What is the Total Fat? _____g

How much Saturated Fat _____g

How much Trans Fat _____g

How much Poly and Monounsaturated Fat _____g

If you had the whole container how much fat is that?

_____ Total fat in 2 servings
 _____ Saturated fat in 2 servings
 _____ Trans Fat in 2 servings

For Next Week:

**Keep track of the fat you eat every day:
“Good Guys vs Bad Guys”**

1. Write down everything you eat and drink.

It's the **most important** part of changing your behavior.

Spelling is **NOT** important. What **IS** important is to:

- Be honest (write down what you really eat).
- Be accurate (measure portions, read labels).
- Be complete (include everything).



Remember: Your lifestyle coach is here to help you!

Next week I will:

Keep track of my weight, what I eat, drink, and my daily activity.

Be active for _____.

Make a plan to change your habit and follow it.

→ Write down in your journal or food diary the foods you circled during today's session.

→ Write down what you will do this week to achieve your goal.
Again, be sure it is **something you can do**.

What I will need to do to reach this goal:

Problems I might have and what I will do to solve them:

Last week we talked about four types of Fat.

Before the session today, answer these questions:

Did you follow your plan? ___ Yes ___ No ___ Almost

What problems did you have following your plan?

What could you do differently next week?

What I will need to do to reach my goal of eating more healthy fat:

Problems I might have doing this and what I will do to solve them:

Session 7: Tip the **Calorie Balance**

This session focuses on the TWO main elements in calorie balance:

- calories consumed or eaten
- calories expended

Calorie balance over time is the key to weight management.

Calorie balance refers to the relationship between calories consumed from foods and beverages and calories expended in normal body functions (i.e., metabolic processes) and through **physical activity**. People cannot control the calories expended in metabolic processes, but they *can* control what they eat and **drink**, as well as how many calories they use up during **physical activity**.











<u>Calories in food</u>	
2 Apples	160
Slice of bread w/	160
1 Tbsp peanut butter	

<u>Calories burned during activity</u>	
30-45 minutes of	170*
upper body circuit training	

*Patrick L. Jacobs, Edward T. Mahoney, Mark S. Nash, Barth A. Green. Circuit resistance training in persons with complete paraplegia. *J of Rehab Res Dev.* 2002; 39(1): 21-28.

Your weight is a result of the **balance** between food (calories in) *and* activity (calories out)

	<u>Food Calories</u>	<u>Activity Calories</u>
1. Your weight can stay the same.		
2. You can gain weight.		
3. You can lose weight.		
4. You can reach a new balance at a new weight		



Remember:

- ❖ Foods eaten and being active work together.
- ❖ To lose weight, it's best to eat less **and** be more active.

- ❖ By **TIPPING** the balance you can lose the weight you want!
- ❖ Over time, you can reach a new balance at a new, lower weight.
- ❖ You will keep the weight off by making changes part of your new lifestyle

How much to **tip** the balance?

- ♀ 1 pound of body fat stores equals about 3,500 calories.
- ♀ Slow, steady weight loss (1-2 pounds/week) is the best way to lose body fat.

To lose:	Tip the balance by this number of calories:
1 pound/week	3,500 per week or 500 each day for 7 days
1-1/2 pounds/week	5,250 per week or 750 each day for 7 days
2 pounds/week	7,000 per week or 1,000 each day for 7 days

For permanent weight loss, it's best to eat less **AND** be more active!

Changes you've made so far



To be more active (both to reach your goal and be active in general)

- _____
- _____
- _____



To eat fewer calories

- _____
- _____
- _____

Have these changes *tipped the balance*?

Your weight at the start of Lifestyle Balance:

Weight now:

Expected weight by this time:

You have:

Stayed at the same weight, or gained weight

- ❖ To lose weight, try something else to tip the balance
- ❖ We'll work together to find what works better for you

Lost some weight, but not as much as expected

- ❖ Good. You've made some progress
- ❖ To lose more weight, try something else to tip the balance *farther*.

Lost as much weight as expected (or more)

- ❖ Great! You've tipped the balance
- ❖ Keep tipping the balance, and you'll keep losing weight

To do next week

I will:

1. Keep track of my weight, eating, and activity.
2. Be active for _____.
 - o Try setting aside one block of time OR find 2-3 shorter time periods.
 - o Plan other activities you LIKE to do.

	What I will do	When	Minutes
Mon			
Tues			
Wed			
Thurs			
Fri			
Sat			
Sun			
Total minutes for the week:			

3. Make active lifestyle choices throughout the day
4. To tip the balance further, I will:
 - o Keep track of calories every day
 - o Watch out for foods that are high in empty calories
 - o Be sure to record *everything*
 - o Watch portion sizes

Portion Size Guide



4 dice = 1 oz of cheese



4-oz individual applesauce = $\frac{1}{2}$ cup



1 small potato = 1 computer mouse = or 1 cup vegetables



Small apple = 1 cup of fruit



8 oz yogurt = 1 cup of milk



School milk carton of milk = 1 cup



$\frac{1}{2}$ medium bagel = 1 hockey puck = 1 oz grain



2 Tbsp peanut butter = 1 golf ball



1 cup pasta = 1 baseball



Session 10: Four Keys to Healthy Eating Out

1. Plan Ahead

- Call ahead to ask about low-fat choices
- Pick where you eat out carefully.
- Go somewhere that offers low-fat choices.
- Eat less fat and fewer calories during other meals that day.
- Eat a little something before you go out or drink a large, low-calorie beverage
- Plan what to order without looking at the menu
- Don't drink alcohol before eating
- For parties or dinner parties: Bring something from home to share with others.

2. Ask for what you want. Be friendly and firm

- Ask for the foods you want
 - Ask for lower-fat foods
 - Can foods be cooked in a different way?
- Don't be afraid to ask for foods that aren't on the menu.
- Ask for the amounts you want
 - Ask how much is usually served.
 - Order salad dressing, gravy, sauces, or spreads "on the side."
 - Ask for less cheese or no cheese.
 - Split a main dish or dessert with someone
 - Order a small size (appetizer, senior citizen's, children's)
 - Before the meal, have the server pack $\frac{1}{2}$ of your order to take home.

3. **Take charge of what's around you**

- Ask for one piece of bread per person instead of a bread basket
- Use olive oil instead of butter for your bread

4. **Choose foods carefully**

- Watch out for these high-saturated fat words on



- | | |
|--------------------------------|------------------|
| • Au gratin | • Hollandaise |
| • Breaded | • Parmesan |
| • Buttered or buttery | • Pastry |
| • Cheese sauce | • Rich |
| • Creamed, creamy, cream sauce | • Sautéed |
| • Fried, deep fried, pan fried | • Scalloped |
| • Gravy | • Southern style |

- Look out for these healthier alternatives



- | | |
|-----------|--------------|
| • Baked | • Poached |
| • Broiled | • Roasted |
| • Boiled | • Steamed |
| • Grilled | • Stir-fried |

- Think about what you really *need* to eat
- Trim visible fat off meat
- Take skin off chicken
- Split main dishes with someone to control portion sizes
- Skip the mayonnaise. Use olive oil instead
- In general:
 - Lunch meals should contain no more than 400 calories
 - Dinner meals should contain around 500 calories

What's on the menu?



- You can make healthier choices no matter what kind of restaurant you go to
 - Be sure to ask the waiter how the food is prepared.
 - Note: Most restaurants serve a tossed salad—top with a dash of olive oil and lemon juice or vinegar.



GO! Healthy choices	CAUTION!
Pizza <ul style="list-style-type: none"> • Plain cheese pizza (ask for half the cheese or low-fat cheese). • Onions, green peppers, mushrooms, tomatoes • Grilled chicken 	Pizza <ul style="list-style-type: none"> • Meat toppings (sausage/pepperoni, ground beef) • Extra cheese
Burger Place (fast food) <ul style="list-style-type: none"> • Grilled, broiled, or roasted chicken, without sauce or mayonnaise • Broiled, extra lean burger. 	Burger Place (fast food) <ul style="list-style-type: none"> • Regular hamburger, cheeseburger. • French fries. • Fried fish or chicken. • Mayonnaise-based sauces.
Mexican <ul style="list-style-type: none"> • Heated (not fried) tortillas. • Grilled chicken or beef fajitas • Soft tacos (corn or flour tortillas). • Salsa or Pico de Gallo 	Mexican <ul style="list-style-type: none"> • Enchiladas. • Chili con queso • Fried tortillas, tortilla chips • Sour cream, guacamole • Crispy or crunchy tacos
Chinese and Japanese <ul style="list-style-type: none"> • Stir-fried chicken. • Stir-fried vegetables. • Steamed rice. • Soup. • Teriyaki. 	Chinese and Japanese <ul style="list-style-type: none"> • Egg foo yung. • Fried chicken, beef, or fish. • Fried rice or noodles. • Egg rolls. • Fried won ton. • Tempura.
Italian <ul style="list-style-type: none"> • Spaghetti with meatless tomato sauce • Minestrone soup 	Italian <ul style="list-style-type: none"> • Sausage • Lasagna, manicotti, other pasta dishes with cheese or cream • Fried or breaded dishes (like veal or eggplant parmesan)



GO! Healthy choices	CAUTION!
Seafood <ul style="list-style-type: none"> • Broiled, baked, or boiled seafood with lemon • Plain baked potato 	Seafood <ul style="list-style-type: none"> • Fried fish • Fried vegetables • French fries
Steakhouses <ul style="list-style-type: none"> • Shrimp cocktail • Broiled chicken or fish • Plain baked potato 	Steakhouses <ul style="list-style-type: none"> • Steak (except trimmed lean cuts). • Fried fish or chicken • Onion rings, other fried vegetables • French fries



Fast Food Options

As you embark on your journey towards a healthier lifestyle it is important to be prepared for the occasional obstacle or bump on the road. Although eating fresh, home prepared meals is always best, below are some convenient options that can fit into your healthy plan for those days when you are *on-the-go*.

 Arby's		 Boston Market	
Menu Item	Calories	Menu Item	Calories
Roast Turkey and Swiss Sandwich (1/2)	340	Qtr. White Rotisserie Chicken (1/2 order) with Steamed Veg and New Potatoes	360

 Burger King		 Domino's	
Menu Item	Calories	Menu Item	Calories
BK Veggie Burger (no cheese)	410	Hand tossed Chicken and Veggie (per slice, small)	210
BK Big Fish Sandwich (1/2 order)	320	Hand tossed Pepperoni Pizza (per slice, small)	238
Spicy Chick'n Crisp Sandwich	300		

			
Menu Item	Calories	Menu Item	Calories
KFC Snacker with Crispy Strip	290	Filet O Fish	380
Grilled Chicken Breast (1/2 order) with Green Beans and Mashed Potatoes n' gravy	240	McChicken	360

			
Menu Item	Calories	Menu Item	Calories
Chicken TROPICHOP w/ rice and beans (1/2 order)	265	Fresco Crunch Taco	150
Chicken TROPICHOP w/ rice and vegetables	165	Fresco Soft Taco – Beef	180
Pork TROPICHOP w/ rice and beans (1/2 order)	340	Fresco Bean Burrito	350
Pork TROPICHOP w/ rice and vegetables (1/2 order)	245	Fresco Burrito Suprema – Chicken	350
1/2 Chicken, white meat (no skin), w/ rice and beans (1/2 order)	350	Fresco Burrito Suprema – Steak	340

Describe a problem you have when you eat out

1. Make a positive action plan using one of the 4 keys to eating out

I will: _____

When? _____

I will do this first: _____

2. I will handle roadblocks that may come up by: _____

3. I will do this to make my success more likely: _____

4. How can we help you? _____

To do next week

- 1. Keep track of my**
 - i. Weight
 - ii. Eating
 - iii. Physical activity

- 2. Try my action plan.**
 - i. Did it work?
 - ii. If not, what went wrong? _____



BEHAVIORAL INTERVENTION- TIMELINE AND PROTOCOL

General Principles:

- 16-session protocol aimed at behavior modification through: education, stress management, problem solving skills training, and cognitive restructuring.
- Delivered by a **Lifestyle Coach** selected with consideration to gender, injury level, and military status.
- 16-session core curriculum training will be scheduled within the 24-week core intervention time frame.
- Individual sessions will be 30-60 minutes in duration.
- Following core curriculum training participants will be contacted monthly for the duration of the extension period.
 - *Face-to-face* contact with the life-style coach will occur bi-monthly.
 - *Off month* contact will be via the **TeleHealth** system.
- A **Lifestyle Manual** will be provided for each participant.

	CORE INTERVENTION TRAINING CURRICULUM.	
	Session	Topic
Focus is on diet and exercise goals and education	1	Introduction to lifestyle intervention. Explain study goals.
	2	Introduce self-monitoring of weight at home.
	3	Teach 3 ways to eat less fat.
	4	Educate about healthy eating. Recommend alternate foods.
	5	Introduce physical activity modules.
	6	Tailor physical activity regimen to needs of the individual.
	7	-Teach principles of energy balance between calories and exercise. -Teach principles of health maintenance from exercise.
	8	-Introduce principles of stimulus control as a method to prevent unhealthy eating. -Introduce principles of stimulus control as a method to maintain exercise adherence.
Focus is on psychosocial and behavioral strategies	9	Present five-step model of problem solving.
	10	Introduce basic skills for eating and exercising away from home. Introduce basic skills for exercising away from home.
	11	Practice identifying negative thoughts and how to counter them.
	12	Introduce concept that slips are part of lifestyle change and provide tips for behavioral change maintenance.
	13	Introduce principles of aerobic fitness and coping with boredom.
	14	Provide strategies for managing social cues, both stressful and supportive.
	15	Summarize stress management principles presented over the course of the intervention.
	16	Focus on enhancing motivation and maintaining behavioral change post-lifestyle intervention.

Session 1A: Welcome to the Lifestyle Balance Program

Objectives:

In this session, the participant will:

- Meet the lifestyle coach and study team.
- Review the Standard Healthy Lifestyle Guidelines, if not presented at randomization.
- Be given the Lifestyle Balance notebook.
- Discuss the participant's initial reaction to being assigned to the Lifestyle Balance group.
- Receive an overview of the Lifestyle Balance Program.
- Learn the two Lifestyle Balance goals and why they are important.
- Discuss key aspects of the coach-participant relationship and sign a related agreement.
- Choose to focus either on the weight loss or the physical activity goal first.

To Do Before the Session:

Get materials ready:

- Keeping Track book (or two, if the next session is scheduled more than 7 days later).
- Pages for participant notebook.
- Video or photographs of local study team members, if not present in person.
- Measuring cups, spoons, and scale (for participants who focus on weight loss first).
- Map to the supervised activity sessions (for participants who focus on activity first).

Invite family member to attend (if, during the run-in period, it was determined that a family member's attendance would enhance adherence).

On the Lifestyle Balance Update page, pencil in tentative appointment dates (schedule sessions 1-8 for one week apart, 9-16 for either one or two weeks apart). Insert this page in to the inside front pocket of the participant's notebook. Also, keep a copy of the Lifestyle Balance Update page in your notes for each participant.

Fill in the activity session schedule on page 1 of Getting Started Being Active.

Introduce yourself and the other members of the local study team.

Greet the participant. Also welcome family member or other support person if present.

Hello. I'm delighted to meet you. My name is []. As you know, you've been assigned to the group in the SCI Weight Loss Program that will be making lifestyle changes to try to prevent diabetes. The lifestyle changes will be to lose weight through healthy eating and to be more physically active. We've called this group the

“Lifestyle Balance Program” because we’ll be helping you reach a healthy balance between what you eat and how active you are.

I will be meeting with you often during the next several years, so we will get to know each other very well. I’m looking forward to working with you as a team to make our time together a success. There are many people on the study team; we’re all resources for you.

Introduce the study team members, or use a video or photographs to introduce them if not present. Explain the role of each member of the team, and stress that during the upcoming years of the study, all of the members of the team will be available to support the participant.

Review the Standard Healthy Lifestyle Guidelines, *if not presented at randomization.*

At this point, I want to quickly go over some standard guidelines for a healthy lifestyle that all participants in the study receive. We give all participants this brochure [show the participant the Koop brochure], which is a good summary of the guidelines, and we talk with all participants about how to be more active [turn to pages 3-10; do not review them, however], eat a healthy diet [turn to pages 11-19], and reach and maintain a healthy weight [turn to pages 20-27]. Because you’re in the lifestyle change group, we will go over these topics in great detail in the coming weeks, so I won’t review them now. But this brochure is for you to take home as a source. Other members of your family might enjoy reading it, too.

We also talk with all participants about smoking and alcohol. Do you now smoke cigarettes?

Give the participant the Lifestyle Balance Notebook.

Here is the notebook we’ll use throughout the study. It’s yours to keep. At every session I’ll give you some handouts to put into the notebook and we’ll go over them together. Feel free to write notes or questions on the handouts, and take the notebook home. Just be sure to bring it with you to every session. Here is my name, address, and phone number for your records [give other team members’ phone numbers, as appropriate].

It’s very important that we stay in touch. Feel free to call me or stop in at the clinic whenever you have questions or need to talk. It’s also important to call if you cannot come to a session.

Discuss the participant’s initial reactions to being assigned to the Lifestyle Balance Program.

Some people who have been assigned to the Lifestyle Balance Program wanted to be in this group from the beginning; some hoped they would be assigned to another group in the study.

- **What do you think about being in the Lifestyle Balance Program?**

- **Are there some things about this group that seem good to you, and some things you're not so excited about?**

The participant may express disappointment about not being randomized to another arm of the study, fears of failing at the lifestyle intervention, memories of past failures at weight loss efforts, and so on. Recognize concerns, promote confidence that the participant can succeed, and give support.

If the participant is very negative, help him or her to identify *some* positive things about being assigned to this approach. Stress that the Lifestyle Balance Program is “state-of-the-art.” It has been carefully designed based on many research studies about the best ways to help people change.

Complete the work sheet “Remember Your Purpose” with the participant.

Emphasize the positive aspects of the intervention, relating them whenever possible to issues of personal value to the participant, and encouraging the participant to provide specific details, in images or words (such as the names of people) that can be recalled later as a source of motivation. Examples:

- Has the real potential to prevent diabetes.
- No drugs, no drug side effects.
- Will reduce his or her risk of heart disease and stroke.
- Will help him or her look and feel better, have more energy.
- Make her or his family and friends proud.
- Set a good example for children, spouse, friends, and community.
- Will contribute to scientific research findings that will then improve health care practices for the community.

Explain that you may review this work sheet with the participant later in the program as a source of motivation.

Receive an overview of the Lifestyle Balance Program.

As I said earlier, the Lifestyle Balance goals will be to:

1. Lose weight through healthy eating, and
2. Be more physically active.

We strongly believe that making these lifestyle changes and keeping them up over time will prevent diabetes in people like you who are at risk of diabetes.

The Lifestyle Balance program has been carefully designed. It is based on many research studies of the best ways to help people change.

In this program we will help you:

- **Learn the facts about healthy eating and being active.** Our staff is experts in nutrition, exercise, and helping people develop healthy habits. We will give you the most up-to-date and accurate information.

But knowing the facts, or what to change, isn't enough. You also need to know **how to change**. So we will help you:

- **Learn what makes it hard for you to eat healthy and be active.**
 - And learn **how to change these things so they work *for you***, not against you.

For example, you'll learn how to:

- Find the time to be active.

[Review the rest of the items on the work sheet.]

We will also give you the **long-term support** you need to stick with the changes you make. We will be your **"coaches."**

Review the Lifestyle Balance Goals.

These are Lifestyle Balance goals:

1. **Lose 7% of your weight through healthy eating.** Your goal will be to weight xxx pounds or less.
2. **Do 2-1/2 hours of brisk, physical activity each week** (this would be like doing brisk exercise for 30 minutes on five days of the week).

We will help you to reach these goals one step at a time and keep them up over time.

We'll go over each of these goals in detail, and exactly what they mean for you, as we go along. You may also have your own specific goals you want to reach, but these are the goals for the study as a whole. I will do everything I can to help you reach the study goals, and so will the rest of the study team.

Refer to the Manual of Operations for how to respond to participants who have their own personal goals, for example, who want to lose less or more weight, who are already very active, or who wish to do less than 2-1/2 hours of activity. Briefly address their concerns, then move onto the study goals. For example:

- If the participant wants to lose less weight or be less active than the study goal: "We'll work toward this goal slowly, one step at a time. It's a safe and reasonable goal for you, and I'm very confident that you can do it."
- If the participant wants to lose more weight or be more active than the study goal: "Let's work toward this goal first. When you reach this goal, we'll talk about going further."

Discuss the rationale for the goals.

The Lifestyle Balance goals are **safe and can be reached**.

We will help you reach the goals by making:

- **Gradual (made one step at a time),**
- **Healthy, and**
- **Reasonable changes in your eating and activity.**

Nothing extreme. For example, you won't need to do very vigorous exercise, although you can if you want. "Being active" doesn't mean you need to be a marathon runner. We will just gradually increase your general activity and help you develop a more active lifestyle.

Reaching the Lifestyle Balance goals:

1. May prevent diabetes.

Research has shown that leaner and more active people are less likely to get diabetes. Also, moderate weight loss and physical activity have been shown to improve the body's use of insulin (the hormone that regulates the amount of sugar in your blood). This can reduce the chance of getting diabetes.

We believe that lifestyle changes can indeed prevent diabetes, if you make these changes and keep them up over time.

That's why you and I will work together to do everything we can to help you lose weight and be more active.

2. Reaching the Lifestyle Balance goals will also help you look and feel better and be more healthy in general. Research has shown that losing weight and being active can:

- Relieve tension, help you relax and sleep.
- Give you more energy, make it easier to get around (for example, if you're more active on a regular basis, your joints will be more flexible and you'll be less likely to injure your back).

Many of you may have health problems like high blood pressure or high blood cholesterol. Research has shown that losing weight and/or being active can:

- Lower blood pressure.
- Lower blood levels of LDL or "bad" cholesterol (the kind linked to the risk of having a heart attack or stroke).
- Raise blood levels of HDL or "good" cholesterol (the kind that reduces your risk of heart attack or stroke).

3. **In addition, reaching the Lifestyle Balance goals will set a good example for your family, friends, and community.**

Many of us live in a family or a culture that practices high-fat eating and inactivity. You will face a challenge as you work at doing things differently. But you will also set a good example of what it's like to live a more healthy lifestyle, which can be inspiring and encouraging to everyone around you.

I know that losing weight and being more active takes a lot of effort. **Changing behavior takes work.** It takes dedication and hanging in there and doing what needs to be done every step of the way.

We are here to help. I'll be meeting with you often, and I will do everything I can over the next four years to help you reach and stick with your Lifestyle Balance goals. I am confident that **you can do it!**

Discuss key aspects of the lifestyle coach-participant relationship.

It is very important that we work together throughout the study as a **team**. I will count on you to:

- **Come to sessions and bring your Lifestyle Balance notebook.**
Call 24 hours ahead if you must miss a meeting. For example, call before Monday afternoon if you must miss a Tuesday afternoon appointment.
- **Do your best to reach your eating and activity goals.** That includes doing home activities to practice what you learn.
- **Keep track of your eating and activity 7 days a week.** I'll talk with you more about this in a few minutes. **Be honest.** Don't try to "please" me. I will count on you to write down what you are really eating, and how active you really are, not what you think I want to hear or what would make me happy.
- **Keep track of your weight at home.** We will also weigh you here at each session. By weighing yourself at home, you will be able to see the pattern of your weight from day to day and see how your changes in eating and activity affect your weight.
- **Let me know if you have any problems.** Ask questions when you don't understand something. I am here to help and I need to know when you're having any difficulties. There's no such thing as a "stupid" question—it's *smart* to speak up when you have a question.

Some participants, because of their cultural heritage or personal history, may consider it rude to ask questions or to bring up difficulties. This is true, for example, of many Hispanics. With these participants in particular, be sure to express your acceptance and appreciation when they voice their questions and concerns.

- **Stay willing and open to change. Always "hang in there."**
 - We will sometimes run into problems, and I will count on you to hang in there and give it your best until we solve the problems together. This is a "can do" study. You can count on me to:
- **Go over your records of what you eat and your activity.**
Notice what you are doing well and what can be improved.

Noticing what you're doing **well** is one of my most important jobs. I will encourage you and build you up and appreciate your efforts.

- **Answer your questions.**

It's important that you feel free to ask me any questions you have, and I will get the answers for you. Please remember that the staff are experts, and our job is to make our expertise available to you in any way we can.

- **Be honest.**

We will both need to "say it like it is." I will count on you to be honest about how you are doing. And you can count on me to tell the truth about how I think you are doing and what I think needs to be done to solve any of the problems we run into.

- **Stand by you during hard times,** and

- **Believe you can reach your eating and activity goals.** We all need someone to believe in us when we are making changes for the better. I know you can do it, and when you get discouraged, I will be here to believe in you. **Always "hang in there" for you, and support and help you continually.**

Is there anything else you'd like me to do to help you? (Write any appropriate suggestions that the participant makes on the work sheet.)

Let's sign this as a way of remembering how we agree to work together.

Sign the agreement and have the participant sign it as well.

We want to be sure this program works for you. No two people are alike. So at different times during the study, you'll be able to choose *when* you want to focus on a certain topic, depending on what will be most helpful to you.

Overview the session topics.

This page shows you the topics for Sessions 1 through 16. As we've said before, you are welcome to invite a family member or friend to any or all of the sessions.

Session 1B: Getting Started Losing Weight

Objectives:

In this session, the participant who has chosen to focus on the weight loss goal first will:

- Learn the reason for self-monitoring foods eaten and the basic principles of self-monitoring.
- Be assigned self-monitoring of foods eaten and circling of high-fat foods; practice this.
- Receive weighing and measuring tools.

Review the reason for self-monitoring foods eaten and the basic principles of self monitoring.

You've decided to start with the weight loss goal. To help you lose weight, our goal is to help you to **eat healthy**. And healthy eating involves **eating less fat**.

This is because **eating too much fat is fattening (makes us fat) and is related to heart disease and diabetes**. (We'll go over this in more detail next week.)

The first step to eating less fat is to **figure out how much fat you are eating now**. To do this, I want you to **write down everything you eat and drink every day**. This is something we're going to do throughout the first 24 weeks of the study. It's the **most important part of changing your behavior**.

For right now, I just want you to write down what you ate, like you did during the run-in.

Keeping track of what you eat will help you and I see, in black and white:

- What foods you eat,
- How much you eat,
- When and where you eat, and
- How your eating habits change over time.

Your Keeping Track records will be the very basis for our working together. You and I will be the only ones to see them, so **spelling is NOT important**.

You can make up **abbreviations** or use your own shorthand if that makes it easier and faster for you to keep track, just so we both know what you mean.

Note: The use of abbreviations may also help those participants who have difficulty spelling feel less self-conscious.

What IS important is to:

- **Be honest.** That means to **write down what you really eat**, not just what you think will please yourself or me.
- Also, **be accurate.** It's best to write down what you eat as soon as possible after you eat it, because it's easy to forget. For example, count the number of slices of cheese you eat and write down the kind of cheese.
- And **be complete. Include everything.** The butter on the toast, the cream in the coffee, and the mayonnaise on the sandwich.

It may seem hard to write down all of your foods, especially at first. And it does take some time. But it's worth its weight in gold. **Being aware of what you are eating is the first step toward changing your eating habits.**

Assign self-monitoring of foods eaten and circling of high-fat foods.

To get you started I want you to do several things during the coming week. They're listed on this part of the work sheet called "To do next week." At every session you'll get a list of one or two things to do during the week. There are square boxes beside each item *[indicate boxes]* so you can put a check beside each one after you do it. That way you'll have a record of what you still need to do before the next session.

For this week, I want you to:

- **Write down everything you eat and drink every day.**

Use this "Keeping Track" book. Give the participant a Keeping Track book and indicate where in the book to record food intake.

Write down the time you eat something, the amount, and the name of the food or drink and a description. **Skip the other columns for now** *[indicate the grams of fat and calories columns]*. Use one line for each food. And **skip activity for now.**

- **Circle some of the foods or beverages you think are highest in fat.** Over time you will learn exactly what foods are high in fat. For now, just guess what some of the foods are. The idea is get you thinking about fat and looking for some of the high-fat foods in your meals and snacks.

Note: You do not want the participant to return with a book more than half filled with circled foods, which would be discouraging. This should be a positive beginning experience.

- Finally, be sure to **bring your completed Keeping Track books and your Lifestyle Balance notebook back with you** to every meeting.

Have the participant practice self-monitoring foods eaten and circling high-fat foods.

Let's take a minute to **practice Keeping Track on this page**. Think about a few of the foods you ate earlier today or yesterday. What was the first thing you ate? When did you eat it? Write the time here, the amount here, and the food here. Just skip the other columns.

Have the participant demonstrate. Be sure the participant understands what to do.
Do you think that food is high in fat? Just guess. If so, circle it.

Continue with several additional foods. Point out, as you go along, examples of accuracy (e.g., give brand name and type of food); honesty (e.g., include nibbles or very large amounts); completeness (e.g., include % fat of milk); and the use of abbreviations.

Just skip the section for physical activity.

Any questions?

Give the participant weighing and measuring tools.

If you want to, you can start to measure the amount of food you eat using these.

Get out the measuring tools.

Here are some **measuring cups and spoons** for you to start to use, just to get an idea of the amount of different foods you usually eat. We'll talk in more detail about measuring in the coming weeks.

For now, you might want to pour your breakfast cereal into the bowl you typically use, just as usual, and then measure the cereal before you eat it. Or put the amount of margarine you usually spread on toast onto the knife and measure it using the measuring spoons before you spread it. You can also use a glass measuring cup, if you have one at home, for liquids and a ruler for measuring things like pizza, pieces of pie, and cookies. This **scale** is for weighing meats and cheese (*briefly demonstrate how to use it*).

As I said, you don't need to measure amounts this week, unless you want to.

Any questions?

Discuss appointment schedule.

We will meet *every week* for the first 8 sessions. On this “Lifestyle Balance Update” page, which we’ll keep in the front of your notebook, I’ve used a pencil to write down some possible appointments for this same time and this same day of the week. Is this a good time for us to keep meeting?

If not, make changes to the penciled-in dates and on your copy of the Lifestyle Balance Update.

For sessions 9 through 16, we’ll meet *[explain the frequency that your clinic has decided to hold these sessions, whether every week or every other week.]* And then, after session 16, we’ll meet once every month or two months.

Session 2: Be a Fat Detective

Objectives

In this session participants will:

- Begin to graph weight and be assigned self-monitoring of weight.
- Learn the reason for and basic principles of self-monitoring fat grams.
- Receive the participant's fat gram goal.
- Practice finding foods in the Fat Counter and figuring out the number of fat grams in foods.
- Learn to calculate a running fat gram total for the day.
- Learn to use the Fat Bank (optional).
- If this is Session 4: Receive weighing and measuring tools. Also, develop an activity plan for the coming week (for most participants, a weekly total of 120 minutes).

To Do Before the Session

Review the participant's self-monitoring records from the run-in period, noting specific examples and general types of high-fat foods consumed.

Get the participant's "How Am I Doing?" graph for weight. The graph should show the participant's weight goal and expected rate of weight loss from randomization weight to the goal.

Using the participant's randomization weight, determine the participant's fat/calorie goals.
Refer to the Manual of Operations.

Get materials ready:

- Measuring cups, spoons, ruler, and scale.
- Fat Counter.
- Keeping Track book.
- Pages for the participant notebook.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities.

Review the participant's Keeping Track for food intake. Notice many good things, and make only one suggestion for improvement.

Were you able to write down anything this week about your eating?
What did you learn by Keeping Track? What difficulties did you have?

If the participant has not self-monitored, ask, "Tell me a little about that." Do your best to uncover some of the barriers that prevented the participant from Keeping Track without making him or her defensive. Problem solve with the participant to address the barriers.

Take a minute to page through the completed Keeping Track book, if available, from front to back. Comment briefly, as described below. (Also, keep the record until the next session or Xerox it. After the session, do a more careful review, make written comments, and return to the participant at the next session.)

Be positive and nonjudgmental. Emphasize what an important learning tool this will be throughout the study. Praise all efforts to keep track, no matter how small, and any level of accuracy or completeness. For example, praise any and all of the following efforts. The participant was able to [this list is for your reference, not to be reviewed with participants]:

- Record anything at all.
- Record something each day.
- Record throughout the day, each day.
- Note time of day.
- Describe kinds of foods (cuts of meat; parts of poultry; label information from packaged foods)
- Describe methods of food preparation: baked, broiled, steamed, stir-fried, fried, barbecued, etc.
- List additions to foods at the table: butter, margarine, cream, sugar etc.
- Give simple details about portion size: counts; cups; bowls; spoonfuls.
- Give actual weights and measures of portion size: package weight ounces, measuring spoons and cups, ruler measurements, food scale measurements.

Examples:

- "Great! I see here that you wrote down eating 13 cheese crackers with your soup."
- "It's really useful that you noted adding 2 teaspoons of butter to your beans."

Point out no more than one area for improvement, preferably starting with the most simple.

Example:

- "I see you were able to record all weekdays. Fantastic! In the coming weeks it will be useful for you to try and record on weekends too so we can learn about how your eating and exercise might be different then."

Weigh the participant. Introduce the How Am I Doing? Graph for weight and self monitoring weight at home.

Today's session is called "Be a Fat Detective" because we'll talk about how to become more aware of the amount of fat you eat and how that can help you lose weight through healthy eating.

Today's session is called "Be a Fat Detective" because we'll be talking about how to become more aware of the amount of fat you eat and how that can help you lose weight through healthy eating.

But before we talk about fat, let's begin today to **keep track of your weight** and your progress toward your weight loss goal.

In the first session we said that one of the study goals was to lose 7% of your weight, which means that, since your **starting weight was xxx pounds**, your **goal is to weigh xxx pounds**. Let's see what you weigh today.

Weigh the participant. See instructions in the Manual of Operations.

To keep track of your weight, we'll do two things. First, at every session we'll **mark your weight on this graph, called "How Am I Doing?"**

Insert the "How Am I Doing?" graph for weight into the front of the participant's notebook.

Here is your "starting weight," what you weighed when you first joined the study, and here is your goal weight. This line shows what a steady and gradual weight loss might look like for you. Of course, most people's weight goes up and down from week to week, and yours will probably do that, too, sometimes above this line, sometimes below it. Many people lose weight faster at first and then the rate levels off. We won't pay as much attention to each weight but rather to the pattern over time. We want you to stay under this line as much as possible and reach your goal weight by Week 24, or six months from now. That will be in *[name the month and mark on the graph at 24 weeks]*. After that we will help you to stay under your goal weight for four years. Maintaining your weight loss will be very important which is why we will teach you not only how to lose weight, but also how to keep it off!

Let's mark your weight for today on the graph.

Have the participant mark it on the graph. Provide help as needed.

When you weigh yourself at the center record your weight here...

Indicate the weight column on the back of the Keeping Track book, and circle the day(s) on which you want the participants to weigh themselves. See Manual of Operations for guidelines.

Introduce the rationale for and the basic principles of self-monitoring fat.

Now let's move on to the topic for today.

To help you lose weight, our goal will be to help you **eat healthy**. And **healthy eating involves eating less fat**, for several reasons.

- First of all, **eating too much fat is “fattening” (makes us fat). So by eating less fat, you can lose weight.**

In fact, fat is the most fattening of all the things we eat. Fat contains more than twice the calories (9 calories per gram) than the same amount of carbohydrate (starch or sugar) or protein (4 calories per gram). So **even small amounts of high fat foods are high in calories.**

Review the example on the worksheet (a lot of calories in a small amount of peanuts versus fewer calories in a large amount of popcorn) and/or other examples that are relevant to the participant's eating pattern.

- **Fat is also related to heart disease and diabetes.** Research has shown that eating a lot of fat can increase your cholesterol level. Cholesterol is one measure of the amount of fat in your blood. The higher your cholesterol, the greater your chance of having a heart attack. There is also some evidence that eating a lot of fat may increase your chances of getting diabetes.

For participants who want more information:

The recent Surgeon General, C. Everett Koop, MD, had this to say about the importance of eating healthy: "If you are among the two out of three Americans who do not smoke or drink excessively, your choice of diet can influence your long-term prospects more than any other action you may take." In other words, healthy eating is one of the most important steps you can take to improve your health.

And in his recent report to the nation, the Surgeon General named eating less fat as our country's number one dietary priority, more important than sodium, sugar, or additives. In fact, all of these important national organizations recommend eating less fat: the National Heart, Lung, and Blood Institute, the American Heart Association, the American Diabetes Association, the American Dietetic Association, and the American Cancer Society.

What kind of foods do you eat that are high in fat?

Let's look at some of the high-fat foods you circled in your Keeping Track. [Write on the work sheet a few of the foods that the participant correctly circled as high in fat.]

What kind of foods do you eat that are high in fat? [If the participant doesn't mention any high-fat foods, briefly look with the participant at this or her self-monitoring records from the run-in period. Write on the work sheet some of the high-fat foods noted.]

Make some general points about the food groups or types of food that tend to be high in fat, such as:

1. Meats (Meats contain both fat that you can see and fat that you can't see.)
2. Dairy foods (whole milk, regular cheese, ice cream) (Many Americans get most of their fat from meats and dairy products, including cheese.)
3. Snacks (such as potato chips)
4. Butter, margarine (Many people add fat to foods to flavor them.)
5. Gravy, mayonnaise
6. Baked goods (such as cookies, cake, muffins)
7. Fat added in cooking (oil, lard, shortening) such as deep-fat frying (fried chicken, French fries, doughnuts).

Keep in mind that the purpose of this list is **not** to give the participant detailed information about where fat is found in foods. Rather, the purpose is to begin to show them that many different foods that they eat are high in fat and to provide a rationale for self-monitoring. The facts about where fat is found in foods should come later as a byproduct of their own discovery through self-monitoring.

These are the kinds of foods you will have to watch out for as you become a "fat detective." They are also the kind of foods that are widely available, tempting to many of us, and they may even be traditional foods in your family or culture.

Many people aren't aware that most of the fat we eat (70% of it, in fact) is hidden in foods.

For example, fat is hidden in:

- The marbling of meats,
- Baked products,
- Sauces, and
- Batter coatings on deep fried foods.

Here's an example. *[Review the example on the worksheet.]* That's a lot of fat, a total of 22 teaspoons or about 1 entire stick of butter or margarine.

The best way to learn how much fat is in food is to **keep track of the amount of fat you eat every day**.

You will need to adapt the following section depending on the participant's literacy level, willingness to self-monitor, and comprehension of the self-monitoring process. If this is Session2, some of the following will be a review of points made at the last session; when possible, make these points using examples from the abbreviated self-monitoring the participant did during the previous week.

The first step is to:

1. **Write down everything you eat and drink in your Keeping Track books.**

This is something we're going to do throughout the first 24 weeks of the study. It is the **most important part of changing your behavior**.

Keeping track of what you eat will help you and I see, in black and white:

- What foods you eat,
- How much you eat,
- When and where you eat, and
- How your eating habits change over time.

Your Keeping Track records will be the very basis for our working together. You and I will be the only ones to see them, so **spelling is NOT important**. You can make up **abbreviations** or use your own shorthand if that makes it easier and faster for you to keep track, just so we both know what you mean.

Note: The use of abbreviations may also help those participants who have difficulty spelling feel less self-conscious.

What IS important is to:

- **Be honest.** That means to **write down what you really eat**, not just what you think will please yourself or me.
- Also, **be accurate**. It's best to write down what you eat as soon as possible after you eat it, because it's easy to forget. For example, count the number of slices of cheese you eat and write down the kind of cheese. Measure portions and read labels (we'll talk in more detail about these things next week).
- And **be complete. Include everything**. The butter on the toast, the cream in the coffee, and the mayonnaise on the sandwich.

It may seem hard to write down all of your foods, especially at first. And it does take some time. But it's worth its weight in gold. **Being aware of what you are eating is the first step toward changing your eating habits.**

2. **Figure out how much fat is in every food and write it down.**

To do this, you will need to:

1. Figure out the amount of the food you ate.
2. Look up each food in the Fat Counter, which is a book I'll give you that lists foods and the grams of fat in each one.
3. Compare the amount of food YOU ate with the amount in the Fat Counter to see how much fat you ate. And third,

3. **Add up the fat grams you eat during the day.**

I'll show you how to do each of these things in just a minute.

Give the fat gram goal.

Everyone in the Lifestyle Balance Program gets a fat gram goal or "budget." It is based on body size and the amount of calories needed to lose weight. So everyone has a different goal.

Your fat gram goal or "budget" is to stay under xx grams of fat each day. You can think of it as a budget because you need to stay *under* it every day. *[Fill in the blank with the participant's fat gram goal (refer to the Manual of Operations).]*

A gram is the way fat in food is measured. A gram is a unit of weight. One paper clip weighs about 1 gram. *[Note: Be careful not to go into too much detail here because some participants may be easily confused by the differences between grams of weight and grams of fat.]*

We don't expect you to stay under your fat gram goal right away or be able to stay under it every day. It may be hard to reach your fat gram goal at first. For now, just try to **get as close to your goal as you can**. During the next few weeks, we will teach you how shop for food and cook and serve it so that it is easier for you to reach your goal. Overtime we'll work together so that you can consistently stay *under* your fat gram goal.

Give the participant the Fat Counter. Demonstrate and practice how to use it and food labels to figure out how much fat the participant eats. *[If this is Session 4, also give the participant measuring tools.]*

This is a Keeping Track of Fat "practice page." Let's write down some of the foods you ate yesterday and figure out the grams of fat in those foods.

Write on the work sheet a variety of foods that the participant ate yesterday. If possible, include both high- and low-fat foods and several foods with portion sizes that might require some calculation on the part of the participant. Show the participant how to look each food up in the Counter and calculate the number of fat grams in the amount that the participant ate.

Exactly how you do this will vary from participant to participant. The key is not to overwhelm those participants who may find calculations difficult and confusing. Assure these participants that you will continue to help them with this in the upcoming sessions and that the **important thing for now is to begin looking foods up in the Counter and getting an idea of the amount of fat in different foods and in various serving sizes.**

As you look foods up in the Counter, give the participant the weighing and measuring tools and make the following points:

Here are some measuring cups and spoons for you to start to use, just to get an idea of the amount of food you usually eat. **Next week we'll go over measuring in more detail and practice it together.**

For now, you might want to pour your breakfast cereal into the bowl you typically use, just as usual, and then measure the cereal before you eat it. Or put the amount of margarine you usually spread on toast onto the knife and measure it using the measuring spoons before you spread it. The glass measuring cup is for liquids. This scale is for weighing meats and cheese (briefly demonstrate how to use it). The ruler is for measuring things like pizza, pieces of pie, and cookies.

Here are some things to keep in mind **when you use the Fat Counter.**

If you can't find a food:

- Look for one that is the most like that food. (Don't assume that a food doesn't contain fat because it's not listed in the Fat Counter.) For example, use nut bread for zucchini bread.
- Write the name of the food in the back of your Fat Counter. There is a section there for listing additional foods. Then ask me about it next week, and I will help you find the fat grams.
- If you are having trouble figuring the grams of fat:
- Just write down the food and the amount you ate. I will help you figure the fat grams when you come in.

If you make a recipe:

- For many recipes, you can simply write down how much of each ingredient you ate. For example, in a stew, write down the amount of each ingredient that was in the amount you ate. For example, how much beef you ate, how much carrots, and so on. Include any fat that you used in cooking.

- If you cook from recipes often, bring in some favorite recipes next week. I will help you count the grams of fat in them.

An optional handout is available on counting fat grams in more complicated recipes. We think that this handout should be saved for a later session, and at this point it would be more appropriate to ask the participant to bring in any recipes he or she uses often and help the participant estimate the fat grams. Remember that the participant is self-monitoring, not recording dietary data for nutrient analyses, and the point is to learn to distinguish high fat from lower-fat foods and make dietary changes toward the fat gram goal.

If you do use the handout at some point, use it to demonstrate how to count the fat grams in one of the participant's own recipes, rather than alone.

The bottom line for this week is to just get started and do your best. If you run into any problems, I'll help you with them next week.

If you eat a packaged food:

- Look on the label for the fat grams. (Even if it is listed in the Fat Counter, the grams on the label are more accurate.) First, find the Nutrition Facts on the label, and look at the serving size. Is this the amount you ate? And look at the total fat grams per serving.
- What if you eat a larger serving than is listed on the label? You will be eating more fat grams than are listed on the label.

Review the sample label on the work sheet. Be sure that the participant understands that the serving size on a label may be very different from what most of us consider a serving.

Demonstrate and practice how to add up fat grams during the day.

Some participants may be confused and overwhelmed at this point because of difficulties with calculations. Do **not** review adding up fat grams with these participants until the beginning of the next session. Instead, simply use the "Adding up the fat grams" worksheet to practice again how to look up fat grams and calculate the number of fat grams in the amount eaten by the participant. As before, tailor this to the participant's skill level.

The final step in keeping track of fat is to add up the fat grams you eat during the day.

There are two ways you can do this in your Keeping Track.

[Turn to Adding Up the Fat Grams work sheet.] Imagine that this is your Keeping Track.

Let's write in some of the foods you ate last week, the amounts you ate, and the grams of fat. In the Grams of Fat column, you can put a slash mark after the number of grams of fat and write down a "running total" (keep adding up the grams of fat throughout the day).

Demonstrate or have the participant calculate several running totals.

A running total is like a subtotal or running balance in a checkbook. The purpose of keeping a running total is so you know just how much fat you've eaten as you go along. You can use this to plan what foods you choose for the rest of the day. For example, "What should I have for lunch? Well, I've eaten x grams of fat so far. My fat gram goal is x grams. So I'd better eat less than x grams of fat for lunch to stay under my fat goal for the day." This is like using a budget to manage how much money you spend.

Another way to add up the fat grams is to use what we call the Fat Bank, these columns that look like rulers. The left column is the Fat Budget. The right is Over Budget.

I'll show you how to use it.

Have the participant do as much of the following as possible. Provide help as needed.

- a. **Your fat goal is x grams. Find that number on the Fat Budget column and put an arrow beside it.** Cross through all of the notches above your goal.
- b. **Then fill in or cross through one notch for each gram of fat you eat.** Start at your fat budget and go DOWN.

Demonstrate or have the participant cross through the notches for the breakfast foods.

You can easily see about how much fat you have left for the day in your budget.

- c. **If you cross through all of the notches in the Fat Budget column, start at the bottom of the Over Budget column and go UP.** This will let you see how much over your fat gram goal you are.
- d. **Write the total fat grams for each day on the back of your Keeping Track booklet** (show the participant where the totals should go). This will help us both to see at a glance how you've done during the entire week.

Have the participant complete the grams of fat, running total, and Fat Bank columns for the rest of the foods on the sample. Also, show the participant where to transfer the total fat grams for the day to the back of the Keeping Track book. Again, be careful not to overwhelm the participant.

Changing the way we eat is a gradual process and it will take time. I don't expect you to be perfect. During the next few months you will learn many different ways to help you eat less fat. For now, I want you to be the best fat detective you can be, looking for fat everywhere. And just do your best to **come as close to your fat gram goal as you can.**

Do you have any questions?

Participants should leave this session aware that:

1. We are more interested in their efforts to be honest and complete about their eating habits than to present us with picture-perfect Keeping Track records, and
2. We consider self-monitoring a very important tool and expect everyone to do some monitoring.

Assign home activity.

For next week:

- Keep track of your weight.
Weigh yourself at home every at this time of day.
Record your weight on the back of the Keeping Track book.
- Keep track of what you eat and drink.
Write down everything you eat and drink in your Keeping Track books.
 - Do this every day, as soon as possible after you eat.
 - Be honest.
 - Measure portions as much as you can and start reading labels.
 - And be sure to include everything you eat.

Use the Fat Counter to figure out how much fat is in what you ate, and write it down in your Keeping Track books. Keep a running fat gram total throughout the day. Try using the Fat Bank, too. Come as close to your fat gram goal as you can.

If this is Session 4:

Keep track of your physical activity, as you have been. And be a little more active this week-- your goal is
(for most participants, it will be 120minutes).

Session 3: Three Ways to Eat Less Fat

Objectives:

In this session, the participant will:

- Review self-monitoring skills, and learn in more detail how to weigh and measure foods, by estimating the amounts of selected high-fat foods, actually measuring the amounts, and then calculating the fat grams.
- Learn three ways to eat less fat.
- Make a plan to eat less fat.
- If this is Session 5: Develop an activity plan for the coming week (for most participants, a weekly total of 150 minutes).

To Do Before the Session

Get materials ready:

- Measuring cups and spoons, glass measuring cup, scale, and ruler.
- Fat Counter.
- Pages for participant notebook.
- Optional handouts that are appropriate for a specific participant (e.g., the blank “Menu Make-Over” work sheet).
- Food models or actual foods for weighing and measuring demonstration. Include a selection of common high-fat foods, plus enough food models of teaspoons of fat (1teaspoon = 4 grams of fat)-or test tubes filled with measured amounts of shortening — to show graphically the fat content of the foods. If possible, choose actual foods that you know the participant eats often. If this isn’t possible, try to use food models that weigh close to what the actual food would weigh to avoid confusing the participant (for example, regarding the weight of various portion sizes of meats). For the actual foods, weigh or measure them in advance. For the food models, tape the amounts on the bottom. Some foods that may be suitable:

To weigh on the scale:

- 3 oz (after cooked) regular (25% fat) hamburger patty (keep frozen) to weigh on scale. 19 grams of fat (equivalent to 5 teaspoons of fat).
- 4 ounces cheddar cheese, thinly sliced by a deli (keep refrigerated). 28 grams of fat(equivalent to 7 teaspoons of fat).

To measure in metal or plastic measuring cup, teaspoon, tablespoon:

- 3 teaspoons of soft margarine in a tub (keep refrigerated). 12 grams of fat (equivalent to 3 teaspoons).
- 4 tablespoons of oil in the bottom of a frying pan, plus same amount in a small jar or bowl. (Ask the participant to guess the amount in the pan first, then bring out the jar or bowl of oil for the participant to measure with a tablespoon). 48 grams of fat (equivalent to 12 teaspoons of fat).

- 1-3/4 cups macaroni and cheese made from a mix (keep refrigerated). 34 grams of fat (equivalent to 8 teaspoons).
- 3 cups of “butter-flavored” movie popcorn. 29 grams of fat (equivalent to 7teaspoons of fat).

To measure in the glass measuring cup:

- 1-1/2 cups of whole milk in a large cereal bowl (keep refrigerated). 12 grams of fat(equivalent to 3 teaspoons of fat).

Weigh the participant. Mark weight on the How Am I Doing? Graph for weight.

If the participant has lost weight, congratulate him or her, but don't go overboard. Stress the fact that he or she must already be making some changes in **behavior**.

If the participant has not lost weight, mention it but stress that little by little as she or he makes behavior changes, the numbers on the scale will change.

Check if the participant weighed himself or herself at home. Discuss the fact that the two scales may differ. Patterns of change should be similar on both (if gain weight on clinic scale, home scale should show a weight gain, also).

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. [If this is session 5, graph activity, also.]

Were you able to write down anything this week about your eating?

What did you learn by Keeping Track? What difficulties did you have?

Were you surprised by the amount of fat in some foods?

How did using the Fat Counter go?

Were you able to keep a running total of fat grams or use the Fat Bank?

How close did you come to your fat gram goal?

Refer to the script for the ‘Be a Fat Detective’ for guidelines on how to review the Keeping Track records.

Review self-monitoring skills using the Fat Counter, weighing and measuring tools, and actual foods or food models.

We've given you measuring cups and spoons and a scale because **weighing and measuring foods is important**. Today we're going to start with something a little more “hands-on” than we've done so far and practice weighing and measuring together. First, let me go over some details about how to use the cups and scale and so on. You may be doing these things already.

Metal or plastic measuring cups and spoons

Use these for solid foods like margarine or mashed potatoes. Fill the cup or spoon and then level it off before you record the amount.

Demonstrate how to level.

Leveling can make a big difference. For example, even two extra tablespoons of granola on top of a cup that hasn't been leveled will add about 3 grams of fat.

Glass measuring cup (demonstrate this, although the study does not provide one)

Use a glass measuring cup, if you have one at home, for liquids like milk or soup. Pour the liquid in the cup, then read the line at eye level. If you read it from above, your eyes can fool you.

Demonstrate measuring liquids and reading the amount from eye level. Use any liquid. Water is fine.

Scale

The best way to measure meat and cheese is on a scale. Even a small amount can make a big difference in fat. Scales can measure very small amounts.

Demonstrate the use of the scale by weighing an actual food or food model. Have the participant weigh another food or food model. Make sure the participant can use the scale and read the results.

It's important to **weigh meats after they are cooked**. They lose about a quarter of their weight in cooking. So 4 ounces of raw meat weighs about 3 ounces when it's cooked. Three ounces of meat is about the size of a deck of cards or your palm, minus the fingers.

When you weigh cheese, you'll notice that one slice might look like another but not weigh the same. For prepackaged slices, you can check the label for the weight.

Most people are surprised when they begin to weigh and measure foods. Our eyes can play tricks on us.

Here are some common high-fat foods that someone might easily eat in a day.

Show the participant food models or actual foods for common high-fat foods. Review the instructions on the work sheet and have the participant complete the chart except for the column "Teaspoons of Fat." If possible, use some actual foods that the participant eats often and observe the participant using the

weighing and measuring tools so you can check her or his technique. Note: It may be helpful to repeat this activity at various points during the intervention, particularly after the Progress Review during Session 7 or 8, 12, and 16, as a way to review measuring skills and demonstrate the importance of accurate portion estimation.

Were you surprised by the actual amounts? Even small mistakes in estimating amounts can make a big difference in the fat grams.

Eventually you will get better at judging food amounts by looking. **For now, weigh and measure foods as often as you can.**

Last week we talked about the fact that most of the fat we eat is hidden in foods (70%, in fact). For example, fat is hidden in:

- The marbling of meats,
- Baked products,
- Sauces, and
- Batter coatings on deep fried foods.

Let me show you what the fat in these foods would look like if we could see it as teaspoons of butter, margarine, or oil. *[Fill in the last column of the worksheet and if possible, illustrate using food models of teaspoons of butter or test tubes of measured amounts of shortening.]* That's a lot of fat, a total of x grams and x pats (or x sticks) of butter or margarine altogether *[note: one stick of butter or margarine = 1/2 cup or 24teaspoons]*. Pretty amazing.

Introduce the three ways to eat less fat.

Many different kinds of foods are high in fat, but there are only three basic ways to eat less fat.

1. **Eat high-fat foods less often.** *[Review the example on the work sheet.]*
2. **Eat smaller amounts of high-fat foods.** Cutting back even a little can make a big difference. *[Review the example.]*
3. **Eat lower-fat foods instead.**

In the coming months, you'll discover a number of ways to "eat lower-fat foods instead." Here are a few examples of the difference you can make. *[Review the examples on the work sheet, including the warning about the calorie content of low-fat or fat-free products. Use other or additional examples if they would be more relevant to the participant's eating pattern.]*

Review the “menu make-over.”

These menus show examples of small changes that make a big difference in fat grams saved. These are examples of the different ways to eat less fat, not menus for you to follow.

You will make your own food choices to reach your fat gram goal.

Review the examples on the worksheet. Mention that potato chips appear in both menus, and explain that there are no “good” or “bad” foods (the participant can eat any food in a small amount now and then and still reach his or her fat gram goal).

A blank “Menu Make-Over” work sheet is available if at this or other sessions the participant would benefit from recording personal examples of high-fat menus and corresponding make-overs.

Assign home activity.

Let's focus now on what you can do next week.

- Keep track of your weight and what you eat. Keep a running fat gram total throughout the day, and try to stay under your fat goal (budget).
*[If this is Session 5] And continue to keep track of your physical activity. This week be a little more active, for a total for the week of. [Fill in the blank. For most participants, the goal will be **150 minutes.**]*
- Make a plan to eat less fat and follow it.

Let's make the plan right now using this chart. First, write down 5 foods you eat that are high in fat. These should be foods that you eat often (not, for example, birthday cake that you eat only rarely). Now circle one of these foods and pick one of the three ways to eat less fat from that food.

Complete the rest of the work sheet with the participant, and assign the questions at the bottom as part of the home activity. Stress that the plan to eat less fat should be specific and realistic.

Session 4: Healthy Eating

Objectives:

In this session, the participant will:

- Discuss how eating less fat fits into the overall context of healthy eating.
- Review the Food Guide Pyramid and its recommendations, including to lower fat.
- Compare the participant's eating pattern to the Food Guide Pyramid.
- Review more examples of ways to eat lower-fat foods instead of high-fat foods.
- Be introduced to the importance of eating more grains, vegetables, and fruits.

To Do Before the Session

Get materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Poster of Food Guide Pyramid.
- Optional handouts that may be appropriate for a specific participant (for example, one on low-fat recipe substitutions for participants who cook from recipes often).
- Individual samples of low-fat foods to taste (optional).

Weigh the participant. Mark weight on the How Am I Doing? Graph for weight.

If the participant has lost weight, congratulate him or her, but don't go overboard. Stress the fact that he or she must already be making some changes in **behavior**.

If the participant has not lost weight, mention it but stress that little by little as she or he makes behavior changes, the numbers on the scale will change.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. [If this is Session 6, graph activity.]

If this is Session 6:

Were you able to follow your activity plan from last week?

Discuss any barriers and problem solve with the participant. Graph on the How Am I Doing? Graph for activity.

What did you learn by Keeping Track last week? What difficulties did you have?
Were you surprised by the amount of fat in some foods?

How did using the Fat Counter go? Did you keep a running total for fat grams?
Did you follow your plan to eat less fat? How close did you come to your fat goal?

Refer to the script for the 'Be a Fat Detective' for guidelines on how to review the Keeping Track records.

Discuss how eating less fat fits into the overall context of healthy eating. Introduce the Food Guide Pyramid.

In the past few weeks, we've talked quite a bit about eating less fat. **Eating less fat is essential to losing weight. It's also one important part of healthy eating in general.** Today we're going to talk about some of the *other* parts of healthy eating. We'll look at your overall eating pattern to see how healthy it is and how you might improve it.

What exactly is "healthy" eating?

One part of healthy eating is the way you eat.

- **A regular pattern of meals is important.** Try to eat 3 meals each day. This will keep you from getting too hungry and losing control.
- **Eat slowly.** You will digest your food better if you take small bites and chew your food well. Also, you'll be more aware of what you are eating and more aware of when you are full. Try pausing between bites, putting down your utensils, and enjoying the taste of your food and the company who may be present.
- **Don't worry about cleaning your plate.** The greatest waste of food is to eat more than you want or need. Practice serving yourself smaller portions to begin with.

Another part of healthy eating is what you eat. One way to define what's included in a healthy eating pattern is by using the **Food Guide Pyramid**. Have you heard of the Food Pyramid? *[Tailor the following discussion based on what the participant already knows about the Food Pyramid.]*

The Food Pyramid is a **general guide to healthy eating** that's based on the latest findings about nutrition and health.

Turn to the Food Pyramid work sheet and point out the base of the pyramid.

The pyramid image is used because at the bottom is the **foundation**, the largest part of the structure, what the rest of the eating pattern is built on.

The foundation of the Food Pyramid is grains, or the **bread, cereal, rice, and pasta group**. These foods should be the main part of your diet. A healthy eating pattern includes **6 to 11 servings** from this group. A generation ago, many families built their meals around meat: the "meat and potatoes"

eating style. Now we know that most Americans eat too much fat and protein, and much of it comes from big servings of meat.

So in the Food Pyramid, the foundation is not meat, but rather breads, cereals, and other grain foods.

After naming the group and stating the recommended number of servings, ask the participant the following questions for every group except fats, oils, and sweets. As you do so, write on the work sheet a few examples of low-fat choices for each group, including serving size.

If possible, use example foods mentioned by the participant. Keep the discussion simple and tailor it to the individual (use examples that match the participant's eating preferences and ethnic background). A Food Pyramid handout on the next page will provide more details for participants who want them about the types of foods and serving sizes in each group. Ethnic variations are available. Do not review the entire Food Pyramid if it would be overwhelming to the participant.

1. **What are some low-fat foods that would fit into this group? What do you think would be considered one serving of these foods?**
2. **Can you think of any high-fat foods that would be in this group? These would be the foods for you to avoid.**
3. For the breads and cereals group: Many people think bread and potatoes and other starchy foods are high in fat, but actually it is the fat added to them in cooking or at the table that makes them high in fat. Potatoes are a good example: plain potatoes are low in fat, but by adding butter or sour cream, they become high in fat.
4. For the meats group: Nuts are included in this group (for example, peanut butter). All nuts are very high in fat. And many meats are high in fat, too. Americans tend to eat too much meat. We used to think we needed to eat a lot of meat to get enough protein, but now we know that Americans tend to eat *too much* protein. The Food Guide Pyramid recommends only two to three servings from the meat group and the portion size for a serving of meat is only 2 to 3 ounces. (Use a food model to illustrate this.) The meats group also includes dried beans. Have you tried dried beans, like kidney beans in chili? Unlike most meats, dried beans are high in protein but low in fat, unless you cook or serve them with added fat.
5. For the milk group: Some people have trouble drinking milk because it gives them gas, bloating, and diarrhea. Is that a problem for you? If so, milk products that are lactose-free may help you get rid of these problems.
6. The smallest part of the Pyramid is at the top, fats, **sweets, and alcohol**. These foods should be eaten **only in small amounts**. In general they don't provide vitamins and minerals, and they are high in calories, "empty" calories. (Remember that fat contains 9 calories per gram and alcohol contains 7 calories per gram, compared to carbohydrates and protein at 4 calories per gram. Small

amounts of sweets won't add many calories, but many sweets, like cakes and chocolate, are also high in fat.)

- a. What are some lower-fat alternatives for foods in this group?
- b. What are some of the high-fat foods to avoid?

Have the participant compare his or her eating pattern to the Food Pyramid recommendations.

Let's look at one or two days from your Keeping Track book and compare what you ate to the guidelines given on the Food Pyramid. *[Turn to Rate Your Plate page.]* Let's start with breakfast and look at how many breads, cereals, rice, and pasta you had.

Move on throughout the day's record, and check off on the Rate Your Plate chart each serving from the food groups. Don't worry about being precise. This is not a self-monitoring record but a general guide to healthy eating. Clarify in simple terms any questions that come up regarding serving sizes.

- Consider one fat serving to be: one teaspoon of butter, margarine, oil, or regular mayonnaise; 1 tablespoon of cream cheese or salad dressing; or 10 peanuts.
- Consider one sweets serving to be: ½ cup of ice cream, 1 small cupcake or piece of cake, or 2 small cookies.
- If the participant drinks alcohol, explain that a) the recommendation is that if you choose to drink alcohol, do so in moderation, and b) alcoholic beverages are high in calories.
- Consider one serving to be one can (12 fluid ounces) of beer (150 calories), one glass (5 fluid ounces) of dry wine (115 calories), or 1.5 fluid ounces (one "shot") of liquor (105 calories). Mixers, such as tonic or a regular soft drink, add more calories.

Continue with a second day if appropriate.

What could you do to better match the Pyramid?

It looks like you could eat more *[vegetables]*. Let's think about tomorrow. If you want to eat 3 to 5 servings of vegetables, how could you do it?

Write example food choices and amounts on the work sheet, total the servings, and compare to the goal number of servings. E.g., 2 servings of salad with nonfat salad dressing for lunch, 1 cooked vegetable and 1 serving salad with nonfat salad dressing for dinner = 4 servings. **Emphasize the importance of increasing grains, vegetables, and fruit.** It is not necessary to complete the rows for every food group.

Provide more examples of ways to "eat lower-fat foods instead."

Last week we talked about the three ways to eat less fat, one of which is to "eat lower-fat foods instead." The Food Pyramid and "eating lower-fat foods instead" work together. Here are some

examples. *[Review the guidelines on the work sheet, highlighting those that are particularly relevant to the participant and reviewing examples from all of the Food Pyramid groups.]*

Do you **cook from recipes**? Or does your spouse? What are some examples?

If the participant does a *great deal* of cooking from recipes, review the guidelines on the optional handout, **Build a Better Recipe**, highlighting those that are particularly relevant to the participant. If the participant only uses recipes occasionally, save the optional handout for a later session because this session is so full of information.

If the participant wants help in lowering the fat in a favorite recipe, have the participant bring the recipe to the next session and modify the recipe with the participant at that time.

Don't review recipe substitutions or modifications at all if the participant seldom cooks from recipes.

For some participants, recipe modification may be helpful as a small part of several future sessions, and it may be important to include other family members who cook for the participant. Regardless, remember that this is an early session and don't try to do too much at this point. Demonstrations of low-fat cooking can be done in future sessions during the maintenance phase of the trial.

Assign home activity.

For next week, I want you to:

- Continue to Keep Track of what you eat *[if this is Session 6, also assign Keeping Track of activity.]*
- For this week only, we're adding one more simple form, the same one we used today to Rate Your Plate. Use the two pages after this one to go over your Keeping Track records and compare what you ate to the Food Pyramid. *[Review the instructions on the forms.]*

Completing the Keeping Track booklet is much more important than completing the Rate Your Plate form. If the participant seems very reluctant to complete the Rate Your Plate forms, mention that you can complete them together at the next session and that the priority is to Keep Track.

Also, answer these questions before our next meeting:

- Did you make any changes during the week to better match the Food Pyramid? If yes, what were they?
- What problems did you have? How did you solve them?

Any questions?

Session 5: Move Those Muscles

Objectives:

In this session, the participant will:

- Receive the Lifestyle Balance activity goal.
- Discuss why the activity goal is important.
- Discuss current level of physical activity.
- Be encouraged to participate in the Lifestyle Balance activity sessions.
- Identify other activities equivalent to brisk exercise that the participant enjoys.
- Discuss the importance of wearing appropriate clothing.
- Develop an activity plan for the coming week (for most participants, this will be a total for the week of 150 minutes of activity) that includes the Lifestyle Balance activity sessions and other moderate activities that the participant enjoys.

To Do Before the Session

Get materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Schedule and map for the supervised activity sessions.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities.

Were you able to come to the Lifestyle Balance activity sessions last week?

Were you able to do something active on 3 to 4 days during the week?

Be positive and nonjudgmental. Praise all efforts to be more active, no matter how small. If the participant did not attend the sessions and/or did not do at least some activity during the week, ask, "Tell me a little about that." Do your best to uncover some of the barriers that prevented the participant from attending or being active without making him or her defensive. Problem solve with the participant to address any barriers. Stress again the important reasons for attending the activity sessions, particularly at the beginning of the study, and for taking steps to be active to some degree on a regular basis.

If this is Session 5 (the last session was "Healthy Eating"):

How did Keeping Track go last week? Did you "Rate Your Plate?" Did you make any changes during the week to better match the Food Pyramid? If yes, what were they? What problems did you have? How did you solve them?

Review and comment on the participant's self-monitoring records. If the participant did not complete the "Rate Your Plate" form, complete the form for one or two days with the participant. Praise all improvements, no matter how small. Problem solve with the participant to address any barriers.

Weigh the participant and graph.

Introduce the Lifestyle Balance activity goal.

So far you've focused on losing weight through healthy eating. This week and next week we'll focus on the other goal of the Lifestyle Balance program: being more active.

The Lifestyle Balance activity goal is to **do a total of 2-1/2 hours of physical activity each week.**
This will burn about **700 calories per week.**

Assess participant's current level of activity.

Now, before we can make an activity plan for you, I need to know **how active you are now.**

The purpose of the following discussion is to get a general idea of how active the participant is and to get the participant talking about his or her personal preferences and experiences with physical activity. Record the participant's answers on the work sheet, and make notations of pertinent details in the participant's progress notes so that you will be able to understand the situations (cues) that promote or derail a participant's physical activity. For example, if a participant has been able to exercise regularly in the past, primarily by doing it at lunch with a coworker, then this valuable piece of information can be highlighted from the start and the participant can be helped to arrange his/her environment accordingly.

- **Do you do any kind of regular physical activity that lasts at least 10-15 minutes?** (Examples: work out at a health club, etc.) Where do you do these activities? With whom?
- How many **times each week** do you do these activities? And when you do, **for how long are you usually active?**
- Have you done any **activities in the past** that you no longer do? Why did you stop? Have you thought about starting to do them again?

If the participant names one or more activities, use them as a starting point when planning for next week.

- **What do you like or dislike about being active or being inactive?** (Record.)

Provide the rationale for the activity goal.

I want to be sure you understand why being more active is so important. **Being more active will:**

- **Help you feel and look better.**
Being active can:

- Improve your mood,
- Counter depression and anxiety,
- Give you more energy,
- Help reduce stress,
- Be a way to meet new friends,
- Help you sleep better,
- Improve your self-esteem (help you to feel better about yourself in general),
- Improve your muscle tone and body measurements.

Many people report that they simply **feel good** when they're more active, and they really miss it if they've been active for a while and then stop.

- Regular physical activity will **make you more physically fit**. It will:
 - Strengthen your heart, lungs, bones and muscles,
 - Make your joints more flexible,
 - Reduce pain and injuries,
 - Make it easier for you to do your daily work, like carrying groceries,
 - Make it easier for you to play with your children or grandchildren.
 - **Help you lose weight and keep it off.**
 - Research has shown that the best way to lose weight is to eat a healthy diet **and** be more active. A combination of both is also the best way to keep weight off.

In addition to helping you lose weight, be more fit, and feel better in general,

- Physical activity will **lower your risk for heart disease, some kinds of cancer, and may help prevent diabetes.**

Being more active:

- Raises HDL cholesterol (the good cholesterol),
- Lowers triglycerides, and
- Lowers blood pressure if it is elevated.
- Being more active also lowers blood sugar by making the body more sensitive to insulin. This reduces the risk of diabetes.

Describe the Lifestyle Balance activity sessions.

It's not easy to start being more active. We are here to help. Some things that can help you are to:

- **Come to the Lifestyle Balance activity sessions!**

List other activities that the participant enjoys that can be counted toward the activity goal.

- It will also help if you **plan activities you LIKE to do.**

After all, the point is to make physical activity a regular part of your lifestyle, and that will never happen unless you enjoy the activities you do. Exercise should be intense **enough to breathe heavier than usual and to consider that you are working hard, but not so fast that you can't carry on a conversation or have trouble breathing.**)

Many kinds of activity are good,. **What other activities might you like to do?**

Write on the work sheet **only the activities the participant should count toward the activity goal**, that is, those that are equivalent to brisk exercise, as indicated in the Lifestyle Intervention.

Manual of Operations. Don't review the list of activities in the Manual of Operations with participants, but use it as your own reference only.

From time to time, the activities you like may change. Just let me know, and we can make changes to this list.

Develop an activity plan for the coming week.

Now let's make a **plan for next week**.

- During the week I want you to **be active for**.

Fill in the blank on the work sheet with the total number of minutes of activity per week (for most participants, this should be **60 minutes**).

For example, you could do xx minutes of activity on 3 different days of the week. We'll gradually increase this over the next three weeks until you're up to 2 ½ hours of new activity per week.

- **Include a friend or family member if you would like.** Some people like to be active alone, as a time to do something special for themselves. But many people find it helpful to be active with someone else. Is there anyone you would like to invite to exercise with you?
- **Include the Lifestyle Balance activity sessions.**
- And remember to **plan activities you LIKE to do.**

Okay. Let's write down the activities you will do on which days of the week. How many minutes will you do them? It should be for **at least 10 minutes**.

- Also, **keep track of your physical activity every day** *[or, if this is Session 5, keep track of your weight, eating, and activity]*. Use your Keeping Track books. Keeping track will help us both to know how you are doing from week to week.

Show the participant where in the Keeping Track book to self-monitor activity. If this is Session 2, you have already shown the participant how and where to self-monitor activity, so the following will be somewhat redundant.

Write down what the activity was and how long you did it. Also, if you're exercising and know the distance in miles, write that down too if you want to. Use one line for each time you're active, even if it's the same kind of activity. For example, if you go around the block at 8:00 in the morning and again at 7:00 in the evening, write both down separately.

It's also important to **record only the amount of time you were actually *doing* the activity**. By that I mean don't include the time when you may have been taking a short break. For example, if you exercised and after 10 minutes you ran into a friend and stopped to talk for 5 minutes before exercising for 10 more minutes, you should only write down 20 minutes of exercise, not 25 minutes. The same is true for when you go swimming. If you are in the water for 60 minutes but only swim laps for 10 of those minutes, then you were only active for 10 minutes and that is what you should write in your Keeping Track.

Session 6: Being Active: A Way of Life

The script for this session is written as if the participant has been relatively sedentary before this time. Use your judgment to change your presentation of the session for those participants who have already been fairly active.

Objectives:

In this session, the participant will:

- Begin to graph activity.
- Discuss time as a barrier to activity.
- Learn two different ways to find the time to be active.
- Discuss lifestyle activity.
- Discuss ways to prevent injury and receive handouts on how to do some simple stretches and when to stop exercising.
- Develop an activity plan for the coming week (for most participants, this will be a weekly total of 90 minutes).

To Do Before the Session

Get materials ready:

- Keeping Track book.
- Pages for participant notebook, including individualized How Am I Doing? graph for activity.

Weigh the participant. Graph the weight in the participant's notebook.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities.

Last week we made a plan for your physical activity. **How did it go?**

Review the participant's Keeping Track records for activity. Praise any physical activity that was done, whether or not the participant reached his or her weekly goal.

If this is Session 6: Also review the participant's dietary self-monitoring and progress toward fat and/or calorie goals and weight loss.

Did you attend any of the activity sessions?

Emphasize again the importance of these sessions, especially at the beginning of the program. If the participant did not attend, try to uncover and address anything that got in the way.

Did you have any trouble Keeping Track of your activity? *[If "yes," review.]*

Graph participant's activity.

Every week we'll **mark your activity on this graph** *[show the participant the How Am I Doing? graph for activity]*. We'll use the graph to see your progress over time and how you are doing compared to your activity goals.

Mark the participant's recorded activity from last week on the graph, or if possible, have the participant do so.

Discuss barriers to activity.

It's important that we try to **solve any problems you're having following your activity plan**. Let's take last week. Did anything get in the way of your plan for activity?

Discuss whatever problems the participant brings up and brainstorm possible solutions. Consider any additional difficulties, such as upcoming cold weather, that the participant may face in the next few weeks and make plans to cope with these. Keep the examples relevant to the present or very near future. Examples:

Problem: Children.
Solution(s): Get a baby sitter or other family member to watch them.
Include the children in the activity (e.g., going for a exercise).

Problem: Hot weather.
Solution(s): Exercise early or late in the day when it is cooler.
Exercise indoors

Problem: Cold weather or rain.
Solution(s): Wear appropriate clothing.

Optional participant handouts are available on various barriers to activity, such as cold or hot weather. Give the participant only those that are relevant at this time.

Discuss time as a barrier.

One of the most common problems is lack of time. Everyone's busy these days.

But you can find the time to be active.

Here are two different ways.

- **Set aside one block of time for planned activity every day.**

Make being active a predictable part of your daily routine, like taking a shower may be a predictable part of your morning.

Use an example that is particularly relevant to the participant's lifestyle. For example, businesspeople may relate to an example of making a "standing appointment" for physical activity. Mothers may relate to an example of planning time to read a bedtime story every night to a child.

When can you set aside 20 to 30 minutes to do an activity you like? Are you a morning person? Or would you enjoy getting out for exercise during lunch? How about after dinner?
[Complete the work sheet.]

Some people can't find one big block of time to be active. Either their schedules vary a lot from day to day, or they're so busy that there isn't a 20-30 minute period that's free on most days. For some people, this might be the case during certain seasons of the year, for example, during the fall when after-school schedules begin to get hectic for their kids.

In these situations, it's usually easier to use a different approach.

- **Be on the lookout during the day for 10 to 15 minutes of free time. Use the time to be active.**

For example, you might be able to take a 10-minute break between meetings at work and go for exercise. Then later, take another 10-minutes to exercise after lunch. In the evening, take 10-minute exercise before you pick your son up from soccer practice. By the end of the day you've done 30 minutes of activity.

In a way, you really can't "plan" for these times, but you can think ahead about when to be on the lookout for them. Or seize the moment! Sometimes all the best planning in the world falls apart. There's still the "spontaneous approach." On some days you might look at the work or housekeeping you have ahead of you and realize, "I'm not going to finish all of this today, no matter what I do." So plan your exercise and JUST GO!

Can you think of any times during the day when you have 10 or 15 free minutes?

[Complete work sheet.]

Discuss lifestyle activity.

We've been talking about the kind of activity you will be recording in your Keeping Track books, whether you do it in one block of time or at several times during the day. Another important kind of activity is called "**lifestyle activity**." It involves **making active choices throughout the day**. It's hard to record this kind of activity, so **we aren't asking you to write it down in your Keeping Track books**. But it is just as important as what you do record.

An example of an inactive choice is when you shop, park your car as close as you can to the entrance to the store. An active choice is to park your car further away and wheel. This may only take a minute or so to do, but every minute of activity has an impact on your overall health and it adds up to a "more active you."

Our parents, and especially our grandparents, didn't have a choice about being active throughout the day. They were active because they had to be. There weren't elevators in every building. They had no car or only one car for the entire family. They had no phone or only one phone and so they ran up or down the stairs to answer it. They did the dishes and laundry by hand. It was simply their way of life. By contrast, most of us now have so many conveniences that our lives are almost guaranteed to be inactive unless we **consciously make active choices**.

What are some active choices you could make during the day? What are some inactive choices you could limit?

Add examples to the chart. Possibilities include:

- Wheel to a nearby store rather than driving.
- Go for a 2-minute exercise session during TV commercials (especially food commercials!).
- Do stretching exercises while watching TV.

Turn inactive time into active time.

Many people say they have no time exercise but they watch several hours of television in the evening. **Try cutting your TV time in half and turn it into exercise time**. Or be active while you watch TV. Lift weights, or exercise with your arms.

At first, you may think of exercise as a way to relax after a long day. But when you get used to it, you'll discover that exercise is a great way to relax and unwind, and you may feel much more rested and refreshed than you would have had you spent that time on the couch in front of the TV.

Discuss ways to prevent injury and give the participant some handouts on simple stretches and when to stop exercising.

- Build up your activity *slowly*. Start and end each session *slowly*. Exercise at a less intense pace is a fine way to warm up and cool down. If you want, you can also do some simple stretches like those on these handouts.

These handouts also tell you what to do if you get a cramp or a muscle strain or pull and when to stop exercising. So look the handouts over at home and we can discuss any questions you have at the next session.

Note: Don't review these handouts during the session. Most participants will simply be wheeling as their form of physical activity, so it is not necessary to emphasize stretching. Just suggest that they start and end their exercise at a slower pace. For those participants who begin doing more intense activity later on, review these handouts at that time.

If a participant starts doing stretches, make sure they do not include stretching time in their 2 1/2-hour goal.

Develop an activity plan for the week.

Now let's make an activity plan for next week.

- The goal is to do a little more than last week, for a weekly total of. *[Fill in the blank on the worksheet. For most participants the goal will be **90 minutes** of activity per week.]*

Try setting aside one block of time, or plan to use several 10-15 minute periods during the day. Include the activity sessions, and be sure to plan activities you LIKE to do. *[Complete the chart.]*

- Also, **keep track** of your physical activity every day. *[If this is Session 6, assign weight and dietary self-monitoring also.]*

Record only the time when you are **doing** the activity. (That is, don't include breaks.) And **don't record activities that last less than 10 minutes**. *[Give the participant a Keeping Track book.]*

- **Include lifestyle activity throughout the day.**
You won't record this, but it is still very important. What active choices do you plan to make during the week?*[Record on the blank line.]*

Next week we'll talk about the lifestyle activity you did.

Any questions?

Session 7: Tip the Calorie Balance

Objectives:

In this session, the participant will:

- Discuss how healthy eating and being active are related in terms of calorie balance.
- Discuss how calorie balance relates to weight loss.
- Review the participant's progress so far in terms of a) changes made in fat/calorie intake and activity, and b) weight change. Discuss how this relates to calorie balance.
- Develop an activity plan for the coming week.
- If weight loss is less than what is expected, make a plan for the coming week to either self-monitor calories or follow a low-calorie meal plan, or both.

To Do Before the Session

Review some of the participant's past Keeping Track records. Make brief notes of some of the positive changes the participant has made to eat less fat and be more active.

For participants who have not lost weight as expected or have gained weight:

Determine the participant's daily calorie goal (refer to the Manual of Operations).

Make sure the participant's How Am I Doing? graphs for weight and activity are up to date.

Have materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Meal plans appropriate for the participant's calorie goal. Tailor to the participant's food preferences as much as possible before the session.

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity? (Graph activity.)

If this is Session 8 (the last session was "Take Charge of What's Around You"):

Were you able to get rid of the problem food cue and add the positive cue for being more active?
What problems did you have? What could you do differently next week?

If this is Session 7 (the last session was “Being Active: A Way of Life”):

Were you able to make the active lifestyle choices you had planned?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Explain how healthy eating and being active are related in terms of calorie balance.

Everything we've covered so far fits together. It fits together because of what's called the "calorie balance." That's what we'll talk about today.

We've said many times that the Lifestyle Balance Program involves **two kinds of lifestyle changes**:

1. Healthy eating. This includes eating less fat and more grains, vegetables, and fruits, and
2. Being active.

These changes are important in and of themselves. They may prevent diabetes and lower your risk of other diseases. They are also important because they're **both related to weight loss** and that's because of what's called "**calorie balance**."

Calorie balance is the balance between the calories (or energy) you take in by eating and the calories (or energy) you use up by being active.

When you eat **food**, you take in calories or energy.

- Calories in food come from **fat, carbohydrates (starches, sugar), protein, or alcohol**. Other ingredients in food, like vitamins, minerals, and fiber, don't have calories. (For example, green leafy vegetables are mostly vitamins, minerals, and fiber--and they have very few calories).
- The **number of calories in any food you eat depends on what's in that food. Fat is the most concentrated in calories, with 9 calories per gram**. That's more than twice the number of calories in starches, sugars, or proteins, and even more than alcohol. So foods that are high in fat are high in calories. That's one important reason why our emphasis has been on eating less fat.

For example, many people think of meats as being “pure protein” but actually most meats contain protein plus a lot of fat, which is where most of the calories in meats come from.

Calories also measure the energy you **use up**.

- You use calories **for just staying alive** (like breathing) and **by any activity** you do.
- The **number of calories you use** in a certain activity depends on several things, including the type of activity, the amount of time you are active, and how much you weigh (basically, the amount of energy used is determined by the amount of weight carried and the distance over which you carry it. When you wheel for a distance of a mile, for example, you are carrying a lot of weight (your body) over a long distance (1 mile).

If the participant is doing a different type of planned activity, check with the exercise physiologist on staff to convert minutes or distance into calories.

Explain how calorie balance is related to weight loss.

Your **weight** is determined by the **balance between food (calories in) and activity (calories out)**.

Let's look at four ways the calorie balance can work.

1. Your weight can **stay the same**. In this case, "calories in" from food equal "calories out" from activity. Food and activity are at about the same level on both sides of the scale.
2. Second, you can **gain weight**. In this case, "calories in" from food are higher than "calories out" from activity. Either calories have increased or activity has decreased or both. The balance has tipped this way *[indicate direction of balance]*.
3. Third, you can **lose weight**. "Calories in" from food are lighter than "calories out" from activity. You've eaten less food (by less I mean fewer calories, not less in volume--remember, we said early in the program that you can actually eat more food for the same number of calories by eating lower-fat foods), or you've done more activity, or both. The best way to lose weight is to do **both** at the same time and **really tip the balance** this way *[indicate direction]*.
4. And finally, you can reach a **new balance at a new weight**. You have developed new food habits and new activity habits and they are balanced again. This is what happens when you lose weight and keep it off. You've reached a new balance over time.

The important thing to **remember** is that:

- **Food and activity work together** to determine how much you weigh.
- To lose weight, it's **best to eat less and be more active**. That way, you are changing both sides of the energy balance at once. **By TIPPING the balance, you can lose the weight you want.**
- Then, over time, you can reach a new balance at a new, lower weight. We will help you to **make the changes part of your lifestyle, so you will keep the weight off.**

Explain calorie requirements for weight loss.

How much do you need to tip the balance in order to lose weight?

The number of calories you need to eat, or the amount of activity you need to do, varies from person to person. But in general, there is a formula we can use. It's based on two facts:

- **1 pound of body fat stores about 3,500 calories**, and
- **Slow, steady weight loss (1 to 2 pounds or so a week) is the best way to lose body fat.** (Quick losses of large amounts of weight can mean that water or muscle are being lost rather than fat, and that's unhealthy.)

So **to lose 1 pound in a week, you need to tip your energy balance by 3,500 calories** in the week. Or 500 calories each day for 7 days. Or to lose 1-1/2 pounds in a week, you need to tip your energy balance by 5,250 calories in the week. Or 750 calories each day for 7 days. For a 2-pound weight loss per week, you need to tip the balance by 7,000 calories in the week, or 1,000 per day.

Again, for weight loss, the best way to tip the balance is to change both food **and** activity.

Review the participant's progress so far in terms of a) changes made in fat/calorie intake and activity, and b) weight change. Discuss how this relates to calorie balance.

Now let's take a minute to review some of the **changes you've made so far** on both sides of the balance.

- First, **what changes have you made to be more active?** We've talked about increasing both planned activity, the kind you've been recording in your Keeping Track books, and lifestyle activity, like taking the stairs instead of an elevator.

Briefly record on the work sheet some of the changes made by the participant. Praise and encourage the maintenance of these changes.

- **What changes have you made to eat less fat (and fewer calories)?** We've focused on eating less fat because fat is the most concentrated source of calories.

Briefly record on the work sheet some of the changes made by the participant. Praise and encourage the maintenance of these changes.

Have these changes tipped the calorie balance?

The answer is in how the scale has responded.

- At the **start of the Lifestyle Balance program, you weighed ...** (*refer to the How Am I Doing? graph for weight at randomization visit and record that weight on the work-sheet*)
- **Your weight now is...** (record on work sheet).

- And **we expected your weight by this time would be ...** (*record the weight indicated on the graph by the expected weight loss line at this week*).

So you have ...

Check one of the three boxes on the work sheet. Be as positive as possible, stressing the accomplishments the participant has made so far, no matter how small, and express your confidence in the participant's future success.

- **Stayed at the same weight, or gained weight.**
 - To lose weight, you need to try something else to tip the calorie balance. We'll work together to find out what will work better for you.
- **Lost some weight, but not as much as expected.**
 - Good. You've made some progress.
 - To lose more weight, you need to try something else to tip the calorie balance *further*.
- **Lost as much weight as expected (or more).**
 - Great! You've tipped the calorie balance.
 - If you keep tipping the balance, you will keep losing weight.

Develop an activity plan for the coming week.

For next week:

- Continue to keep track of your weight, eating, and activity.
Be active for _____ .

Fill in the blank on the work sheet, depending on how active the participant has been until this point. For most participants, *if this is Session 8*, the goal should be **150 minutes** per week; *if this is Session 7*, the goal should be **120 minutes** per week.

By doing more activity, you will use more calories.

As before, try setting aside one block of time each day, or look for 10 to 15 minutes that open up during the day and use them to be active. Include the Lifestyle Balance activity sessions. And plan other activities you **LIKE** to do. *[Complete the chart.]*

- **Make active lifestyle choices throughout the day.** As we've said before, every minute of activity is helpful. So keep moving as much as you can.
What are some of the active choices you plan to make this week? *[Fill in the blank.]*

If weight loss has not been as expected, make a plan for the coming week to either self-monitor calories or follow a low-calorie meal plan, or both.

The following is a requirement for participants who have not lost as much weight as expected. It is an option for successful participants who want to lose more weight or express an interest in learning more about the calorie content of foods.

- **And to tip the calorie balance further, one of two things will be helpful:**
 - **Keep track of calories every day, just like you've done for fat grams.**

Sometimes it isn't enough to just look at fat grams. You may be eating some foods that are relatively low in fat but still high in calories. (For example, many of the new fat-free frozen desserts and cookies are just as high (or higher) in calories than the original versions because of added sugar.) Or you may be eating large enough portions of some foods that the calories are adding up. By keeping track of calories, you'll learn which foods are higher in calories and find ways to save calories. So this week, we want you to look up the calories in every food you eat, just like you've been looking up the fat grams.

Try to stay under calories each day. You should lose weight if you eat that number of calories. Also,

- Watch out for the foods that are high in calories.
- Be sure to record *everything*.
- And watch portion sizes.

Or it might be most helpful for you to:

- **Follow a meal plan for calories per day.**

A meal plan is a model or good example of what to eat. A meal plan will:

- **Show you exactly what foods and amounts to eat.** You won't be faced with a lot of decisions and temptations about food.
- A meal plan will also **make it easier for you to record what you eat.** In fact, if you follow the meal plan *exactly*, you won't need to record anything.

Which do you think would be most helpful, keeping track of calories or following a meal plan? Or would you like to try both?

Check the box or boxes on the work sheet.

- If applicable, give the participant the appropriate meal plans. Tailor the meal plan to suit the participant's food preferences, and answer any questions or concerns the participant has regarding following the meal plans as closely as possible for the coming week. Present the meal plan as a flexible model from which the participant can develop an individualized eating style, rather than as

a rigid prescription. (See How to Use the Lifestyle Balance Meal Plans for further information on how to introduce the meal plans to participants.)

- With some participants, you may need to practice calorie monitoring using an example and/or briefly double-check and correct portion estimation skills using food models.

For the rest of the study, we'll keep working together to bring you closer to your weight loss and activity goals. **We'll keep trying to tip the calorie balance and see how the scales respond.** Over time, you'll reach a new balance at your goal weight and then we'll work together to help you maintain that weight.

Note: The following explanation is for only those participants who express interest in how their calorie goal has been calculated. Do not give this text to participants.

Question: How did you determine the number of calories I should be eating to lose weight?

Answer: The number of calories you need for weight loss depends on many things, including how active you are, how old you are, and so on. But we can make a good guess and then see how the scale responds. We like to begin by estimating what you ate when you entered the program.

1. Estimate of what you ate when you started:

Starting weight x 12 = calories/day (estimate)

2. A slow, steady weight loss of 1 to 2 pounds per week is the best goal.

- To lose 1 pound, you must eat 3,500 calories less. If you want to lose 1 pound in 1 week, you would need to eat 500 fewer calories each day for 7 days.
- To lose 2 pounds, you must eat 7,000 calories less. If you want to lose 2 pounds in 1 week, you would need to eat 1,000 fewer calories each day for 7 days.

We recommend that heavier people aim to lose 2 pounds per week, and that thinner people lose 1 pound per week. No one should eat fewer than 1,000 calories/day.

3. Estimated calories at start: calories/day for maintenance

To lose 1 pound per week, subtract 500 to get calories/day.

To lose 2 pounds per week, subtract 1000 to get calories/day.

So your daily calorie goal for weight loss is _____.

Session 8:

Take Charge of What's Around You

Objectives:

In this session, the participant will:

- Learn about food and activity cues and ways to change them.
- Mentally search the participant's home, work place, and where the participant shops for food, looking for problem food cues and discussing ways to change them.
- Learn ways to add positive cues for activity and get rid of cues for inactivity.
- Develop an activity plan for the coming week (150 minutes per week).

To Do Before the Session:

Get materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Optional handouts that may be appropriate for specific participants (for example, the "Am I Really Hungry?" sign to post on the refrigerator door).

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity? (Graph activity.)

Did you "Rate Your Plate?" Did you make any changes during the week to improve the way you eat (eat more slowly, follow a regular pattern of meals/snacks)? Did you make any changes to better match the Food Pyramid? If yes, what were they? What problems did you have? How did you solve them?

If the participant did not complete the "Rate Your Plate" form, complete the form for one or two days with the participant.

Were you able to make the active lifestyle choices you had planned? Keep track of calories and stay under your calorie goal and/or follow the meal plan (*if applicable*)? Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Introduce the concept of eating and activity cues.

Today we're going to talk about **taking charge of what's around you**, or **how to make what's around you support your Lifestyle Balance goals** to lose weight by healthy eating and to be more active.

First, we'll talk about cues for eating, and later, go on to activity cues.

What "cues" you (or makes you want) to eat?

- Of course, one reason we eat is because of **hunger**. But what about those times when you have an "appetite" or desire to eat without physically being hungry?
- You might eat because of **what you're thinking or feeling**. For example, you might eat some ice cream because you feel lonely, bored, or happy.
- You might eat because of **what other people say and do**. You might eat chips at a party because a friend offers them to you.
- Or you might eat because of **the sight or smell of food, or**
- **Certain activities that make you think about food** (like watching TV or reading magazines). This is what we'll focus on today. In later meetings we'll talk about eating in response to thoughts, feelings, or what other people say and do.

The **sight of food** is one of the most powerful food cues. For example, you may see a carton of ice cream in the freezer and soon you'll be eating ice cream, even though you're not hungry. The **activity of watching TV** is also a powerful food cue for many people. You may turn on the TV and find yourself eating potato chips, even though you're not hungry.

Another example is **eating popcorn at the movies**. Do you eat popcorn when you go to the movies?

If not, probe for another example that is relevant for the participant, such as eating hot dogs at a sporting event or buying cookies after passing a bakery. Use the example in the discussions that follow.

Why do you eat popcorn in that situation? Do you think it's because you're hungry?
Most likely, it's because eating popcorn at the movies is a **habit** for you.

When you respond to a food cue in the same way over and over again, you build a habit.
The food cue becomes paired with the way you respond, and your response becomes more and more automatic.

Let's say that since childhood, you've gone to the movies many, many times, and you've eaten many boxes of popcorn there. Now you find yourself eating popcorn whenever you go to the movies, even though you're not hungry. You responded to the cue (going to the movies) in the

same way (buying popcorn), over and over again. Buying popcorn became a habit. And since it's a habit, it may be hard for you to sit through a movie and not have popcorn.

Food cues and eating habits are not harmful by themselves. But they can be a problem if they get in the way of your efforts to eat less fat and calories.

Discuss two ways to change problem food cues and habits.

How can you change problem food cues and habits?

1. One of the best things you can do is to **stay away from the food cue. Or keep it out of sight.** For example, you may not be willing to stop going to the movies, but you can stay away from the concession stand. If you keep going to the movies and don't let yourself have popcorn, slowly you will stop thinking about popcorn. The connection between the movies and the popcorn will have been broken.
2. Or you can **build a new, healthier habit. Practice responding to the cue in a healthier way.** An excellent way to support yourself as you do this is to **add a new cue that helps you lead a healthier life.** For example, you might take a package of sugar-free gum with you when you go to the movies. When you enter the theater, take out a piece of gum. After a while, you will connect going to the movies with chewing gum.

It's important to remember that **it takes time to break an old habit or build a new one.** Change doesn't happen overnight. If you wanted to stop eating popcorn at the movies, you would need to see a lot of movies without popcorn. Eventually, you will enjoy the movie and forget about the popcorn.

Note: Some participants will find it hard to accept the idea that cues in the environment make them want to eat certain things. Try to find some ways (for example, as in the bullets below) to show the participant that there are many food cues around us all the time and that this phenomenon is so common that we are usually unaware of how powerful it is.

These ideas are powerful, and they work. Also, they're nothing new. People use them every day, sometimes very consciously and sometimes without even thinking about it. Some examples:

- Food companies deliver samples of new breakfast cereals right to your door by mail. They know that if they can get the food into your house, you'll eat it.
- For generations, mothers have put leftover snacks in the front of the refrigerator so their teenagers are more likely to eat them before the foods spoil.
- Supermarkets put new products on the shelves that are the easiest to see and reach.

In this session, we want to help you learn to make changes in what's around you to encourage healthy eating and being more active.

Identify specific food cues at home that are a problem for the participant. Discuss ways to change them.

Let's talk about **some of the problem food cues in your life and some ways you can change them.**

Note: A few common food cues are listed at the top of the second work sheet. Do not turn to this yet.

Let's start with **where you live**. Imagine that we've just opened the front door. We have a video camera, and we start taking a video of what's in the room. Which room would it be? Do you see any actual food in the room? Do you see anything else that might make you think about eating, like a TV or a comfortable chair? What is a change you could make to stay away from that cue or to build a new, healthier habit?

Move from room to room ("Are there other rooms that are a problem for you?"), asking for cues and discussing possible ways to either stay away from the cue or to build a new, healthier habit. If the participant has no response, refer to previous Keeping Track records and/or turn the page in the participant's notebook to the list of common problem food cues and ask if one or two of the examples apply to the participant (possible solutions are given below). Don't give too many examples. Some will undoubtedly come up at future sessions and can be addressed in detail at that time. The purpose of discussing specific examples is to make the "remember" points that follow of relevance to the participant.

Living room (or bedroom)

Cue: *TV (or computer, telephone).*

Solution(s): One way to break the connection between eating and the TV is to make it a rule never eat while watching TV (or on the computer or phone).

Keep an exercise band near the TV.

Keep a pack of sugar-free gum near the TV (or computer). Allow yourself only gum while watching TV (or working on the computer).

Cue: *Candy dishes (for serving candy, chips, and nuts) on an end table.*

Solution(s): Don't buy the candy, chips, or nuts.

If you must buy these foods, hide them. Keep them out of sight.

Kitchen

Cue: *High-fat/calorie foods, **especially those that are ready to eat**. In the freezer (e.g. ice cream), refrigerator (e.g., cheese, lunch meats, whole milk, pie), kitchen*

cupboards (e.g., cookies, chips), or on counter tops (e.g., cookie jar, food packages).

Solution(s): Stop buying these foods altogether.
Store them out of sight, in a brown bag or other unattractive, opaque container.
Make them hard to reach.
Keep lower-fat/calorie choices easy to reach, in sight, and ready to eat.
Examples: Fresh fruits, raw vegetables (already washed and prepared), non fat dips, pretzels, low-fat popcorn, diet drinks.
Limit high-fat/calorie choices to those that require preparation.

Cue: *Foods you are cooking or leftovers, on the stove or counter.*

Solution(s): Make it a rule not to eat while cooking.
Taste foods only once, then rinse your mouth with water or a breath mint immediately.
Rinse off any utensils used in food preparation immediately after each use.
Ask someone else to taste the food.
Put leftovers away **before** meals.
Ask someone else to put the leftovers away.
Put leftovers in individual serving containers right away, and freeze them for future meals.

Dinner Table

Cue: *Serving dishes or packages of food on the table during meals.*

Solution: Serve foods from the kitchen.
Store food only in the kitchen. Put packages away immediately after use.

Cue: *Large dinner plates (or large glasses, bowls, serving spoons and forks).*

Solution(s): Serve yourself small portions using a smaller plate or bowl. Or ask someone who is supportive to do so. Spread the food attractively over the plate.

Cue: *Leftovers on plates.*

Solution(s): Remove your plate from the table as soon as you're finished.
Don't eat the food that your children leave on their plates.

Identify specific food cues at work that are a problem for the participant. Discuss ways to change them.

Let's do the same thing with **where you work**. Are there any things on your way to work, around you at work, or on your way home that have become paired with eating high-fat/calorie foods?

Cue: *Fast-food restaurant (or bakery, hot dog stand, candy store, etc.) on the way to or from work.*

Solution(s): Take a different way to work.
Make it a rule to never eat in the car.

Cue: *High-fat/calorie foods in public areas* (doughnuts or high-fat coffee creamers near the coffee pot, candy on secretary's desk, etc.).

Solution(s): Stay away from those areas.
Buy or make your own coffee in a different place.
Bring a low-fat/calorie snack to share with co-workers.
See if there's a way to keep these foods out of sight (other co-workers may appreciate it, too).

Cue: *High-fat/calorie foods on your desk, in your desk drawer, or in your locker.*

Solution(s): Don't bring high-fat/calorie foods to work. Keep low-fat/calorie snacks like apples, raw carrots, pretzels, low-fat popcorn, or diet beverages on hand instead.
Make it a rule not to eat at your desk.

Cue: *Vending machines.*

Solution(s): Stay away from the vending machines.
Bring a low-fat/calorie snack from home. Or buy juice or pretzels, if available in the machine. Ask a friend to go get them for you, so you won't be tempted by the other foods.

The important thing to **remember**, whether you are at home or at work, is:

1. **Keep high-fat/calorie foods out of your house and work place. Or keep them out of sight.**
Out of sight is out of mind.

Keep lower-fat/calorie choices easy to reach, in sight, and ready to eat.

Examples: Fresh fruits, raw vegetables (already washed and prepared), non fat dips, pretzels, low-fat popcorn, diet drinks.

2. **Limit your eating to one place.** Where do you eat most of your meals at home? Limit all eating to this place. When you are hungry, go to this place to eat. This will help you to distinguish between hunger and other cues to eat.

At work, a particular table in the cafeteria or kitchen area may be a good choice. Do not eat at your desk or computer. This is an open invitation to become distracted from eating.

3. **When you eat, limit other activities.** The rule is simple: No TV, driving, or talking on the phone while you are eating. Focus on enjoying the meal. In the future, these other activities will not cue you to eat.

Identify specific food cues while shopping for food that are a problem for the participant. Discuss ways to change them.

Finally, let's take the video camera to **where you shop for food**. Move around the store as you usually do. What do you see that's a problem for you?

You don't have as much control over what foods are in the grocery store as you do over what foods are in your house. But you do have some control. Here are some tips:

- **Make a shopping list ahead of time.** Make it a rule not to buy anything that's not on the list.
- **Don't go shopping when you're hungry.** Have a low-fat/calorie meal or snack first.
- **Avoid sections in the store that are tempting** to you, if possible. For example, go down a different aisle to avoid the bakery.
- **Ask the grocery store manager to order low-fat/calorie foods** that you want to buy. Remember, that is their business, to please you, the customer.
- **Don't be a slave to coupons.** Only use the coupons that are for low-fat/calorie foods, not for high-fat foods.

Identify specific positive cues for activity that the participant could add to his or her home.

Now let's turn to **physical activity**. For most people, there are many things around them that lead to being inactive. For example, after dinner, you may automatically position yourself in front of the TV. This is because the end of dinner and TV have been paired together many times in the past. But remember, you do have a choice. You could just as easily choose to exercise after dinner.

If you have been inactive, you probably have many cues around you that are associated with inactivity and few that would cue you to be active. To be active regularly, it's important to add positive activity cues to your life. Over time, the cues will become paired with being active, and you will develop new activity habits that will become more and more automatic.

What are some positive activity cues that you could add to your life? Let's pick up our imaginary video again, and start with **where you live**. What could you add to the living room that would prompt you to be active?

Move from **room to room**. Mention a few examples from the handout and add some that are particularly relevant to the participant.

In the living room or bedroom:

- Keep exercise equipment in sight, not in the closet.
- Hang an activity calendar and graph of your activity in a visible place.
- Keep an exercise band near the TV. (Why not make TV a positive cue?)
- Hang a photo or poster of people being active or of outdoor scenes in a visible place.
- Subscribe to a health or exercise magazine. Keep it in a visible place.
- Buy a home exercise video and leave it on the coffee table or on the TV.
- Put a note on the TV reminding you that a half hour of TV time could be used for exercise instead.

In the kitchen:

- Post motivational photos, outdoor scenes, or reminders to be active on the refrigerator.

In the bathroom:

- Post a reminder on the mirror before breakfast.

Identify positive cues for activity that the participant could add to his or her work place.

What are some positive activity cues that you could add to your work place? Let's pick up our imaginary video again. *[Mention a few examples from the handout and add some that are particularly relevant to the participant.]*

- Put your exercise band in a visible place in your office.
- Put a note on your office door reminding yourself to exercise during your lunch break before eating.
- Set an alarm on your watch to remind you to exercise.
- Make a regular, daily appointment with yourself to be active. Write it in your date book. Keep your appointments with yourself—they are as important as your other appointments.

Emphasize two cues that can prompt activity either at home or work.

- Set up a **regular "date" to be active with a friend or family member.** When she or he arrives at 7:00 for exercise, you'll probably go even if you don't feel very energetic.
- **Use a timer or alarm on your watch to remind you to be active.**

Discuss some ways to remove cues for inactivity.

Another approach is to remove the cues for being inactive.

- **Watch less TV.** Keep the TV behind closed doors in a cabinet. Or get rid of your TV. Or be active while you watch TV (for example, use your exercise band or system).
- **Don't leave things in a pile around the house.** They remind you to keep leaving more things there, rather than putting them away. Take separate trips to put them away instead.

In summary, it takes time to break old habits and build new, healthier ones, but it can be done. One of the most important steps you can take is to get rid of problem cues and add new ones that will help you lead a healthier life. **You can make food and activity cues work FOR you, not against you.**

Assign home activity.

Here is what I want you to do next week. First, get rid of one problem food cue in your life. Let's make a plan for that. *(Ask the participant the questions on the work sheet and fill in the blanks).* Also, add one positive cue for being more active. *(Ask the participant the questions on the work sheet and fill in the blanks).* What problems do you think you might have in trying to make these changes? How will you deal with them?

As always, keep track of your weight, eating and activity and do your best to reach your goals (specify goals on cover of Keeping Track books).

Finally, answer these questions before you come in to the next meeting ("Did you follow your plan?" and so on). We'll talk about how you did when you come in next week.

Any questions?

Session 9: Problem Solving

Objectives:

In this session, the participant will:

- Learn the five steps to problem solving.
- Practice the steps using a problem the participant is experiencing now with eating less fat/calories or being more active.

To Do Before the Session

Have materials ready:

- Keeping Track book.
- Pages for participant notebook.

Weigh the participant.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Review Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity?

Graph physical activity.

Were you able to get rid of the problem food cue and add the positive cue for being more active? What problems did you have? What could you do differently next week?

Were you able to make the active lifestyle choices you had planned? Keep track of calories and stay under your calorie goal and/or follow the meal plan (*if applicable*)?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Introduce the upcoming sessions and the problem solving process.

In the first eight sessions of the Lifestyle Balance program, you learned *how* to eat healthy and be more active. Healthy eating and being active will help you lose weight and be healthier in general. We also hope it will reduce your chance of developing diabetes.

But healthy eating and being more active means changing your habits, and making the changes a permanent part of your lifestyle. Many things can get in the way of changing habits. That's what we'll focus on in the next several sessions. We will discuss:

- Negative thoughts,
- Slips and your reactions to slips (a slip is when you don't follow your eating or activity plan),
- Stress, and
- What people say and do (or "social cues").

All of these things can get in the way of healthy eating and being more active.

What are some examples of things that get in the way for you?

Name several problems that the participant has already discussed at earlier meetings, if possible. E.g., You wanted to go out for exercise, but it was too cold. You wanted to eat less fat, but your children wanted you to buy potato chips.

It's inevitable that problems like these will come up.

But problems can be solved. Today we're going to talk about the *process* of problem solving. This is the process that you and I will be working on together throughout the study.

Explain the five steps to problem solving.

In general, there are five steps to solving problems.

1. The first step is to **describe the problem in detail. Be specific.**

For example, instead of defining the problem as "I eat more fat than I should," be specific about the kinds of foods you eat that are high in fat--maybe high-fat desserts or red meats. Be specific about when you eat them, and describe these situations in detail. For example, you may eat high-fat desserts when you go to your mother's house and she offers them to you.

Also, **look at what led up to the problem.** Many problems involve a chain of actions: one action leads to another and then another and eventually this leads to inactivity or overeating. This is called an "**action (or behavior) chain.**"

Try to see the steps (or "links") in the action chain, including:

- **Things around you that cue (or prompt) you to eat or to be inactive.**
We've talked about food and activity cues before. Examples are a bakery near where you work, television watching, or a carton of ice cream in your freezer.

- **People in your life who don't support your efforts** to lose weight and be more active. Examples are a co-worker who offers you doughnuts every morning, children who insist that you deep-fry chicken rather than baking it, or a spouse who wants you to watch TV in the evening rather than exercise.
- **Thoughts or feelings that get in your way.** Examples are defeating thoughts like, "I'll never be disciplined enough to exercise every night." Or feelings of boredom, stress, loneliness, or anger that lead to overeating.

Here is an example of an action chain *[refer to the diagram]*:

Sarah is a busy woman with a job and a family. Yesterday she was extremely busy at work and she **didn't eat lunch** because she didn't have time to go out. In the afternoon, her **boss was very critical** and demanding, and **Sarah felt stressed and anxious**. At the end of the day, Sarah **came home tired, upset, and hungry**. She **went right to the kitchen**. She immediately **saw a package of cookies on the kitchen counter**, and before she knew it, she **ate a fair number of the cookies**.

It may seem complicated to look at a problem in this much detail. But actually, it makes problem solving much, much simpler.

- You see that the real problem may not be the last step (eating the cookies) but rather all of **the things that led up to it** (like not eating lunch and soon).
 - Uncovering the action chain will help you to **find the "weakest links" in the chain to break**. There's a saying that a chain is only as strong as its weakest link. By naming all of the links in the chain, you will be able to find the weakest ones, the places where you can make a change most easily.
2. Step 2 is to **brainstorm your options**. What are all of the possible solutions to the problem? "Brainstorming" means to create a storm of ideas in your brain. Let the ideas pour out, no matter how crazy they may seem. Anything goes. The more ideas the better. And it's actually helpful to include some crazy, extreme ideas because it helps open your mind and stir up your creative juices.

By brainstorming, **you'll see that you aren't at all powerless to change your situation**. You have many options. Here are some possible ones for Sarah *[refer to work sheet]*.

3. Third, **pick an option to try**. Weigh the pros and cons of each option, and choose one (or it might be a combination of several) that is **very likely to work** and that **you can do**. In other words, be realistic. You should be confident that you will succeed.

It's also helpful to try to **break as many links as you can, as early as you can** in the chain.

For example, it will be much easier for Sarah to control her eating in the evening if she eats some lunch and doesn't arrive home hungry. It will be easier for Sarah to avoid eating too many cookies if she doesn't buy the cookies in the first place. Another reason to try to break an action chain as early as possible is that **you will have more links to work with**.

If eating lunch doesn't help Sarah and she still arrives home tired, upset, and hungry, she can still choose low-calorie snacks like fruit when she gets home.

Let's say that Sarah chooses the option of packing a quick bag lunch.

4. Fourth, **make a positive action plan**. This is where you spell out exactly:

- What you will do,
- When you will do it, and
- What you need to do first.
- Also, make a plan for any roadblocks that might come up,
- And build in steps that will make success more likely. For example:
Will it help you to involve someone else?
Can you do anything to make it more fun and enjoyable?
Will it help if you:

Write your plan down and post it on your refrigerator or calendar?

Tell your plan to someone else, so you're committed to following it?

Join an exercise class or club so you're more committed?

Make a date with someone to exercise?

Sometimes if you build in a step to get yourself over the first "hump," then everything begins to snowball and the rest is much easier. For example, here is Sarah's action plan *[review work sheet]*.

5. The fifth step of problem-solving is to **try it and see how it goes**. Did it work? If not, what went wrong? Use what you have learned to problem solve again and make a new action plan. Remember, **problem solving is a process. Don't give up**. It often takes many tries to find a solution.

Review another example if you think it would be helpful. Use one that is tailored to the individual (for instance, an example of the food preferences of the family getting in the way of the participant's goals).

Now let's apply this process to you.

Have the participant practice the steps using a problem he or she is experiencing now.

For next week, I want you to work on solving a particular problem. Think of a problem that you're having now with eating less fat/calories or being more active.

Complete the **Lifestyle Balance Problem Solver** work sheet with the participant.

For next week:

- Keep track of your weight, eating, and activity.
- Follow your action plan. And answer the questions on the work sheet.

Session 10: Four Keys to Healthy Eating Out

Objectives:

In this session, the participant will:

- Learn four basic principles for healthy eating out: **planning ahead, assertion, stimulus control, and healthy food choices.**
- Identify specific examples of how to apply these principles at the type of restaurant the participant frequents.
- Practice making a meal selection from an appropriate menu.
- Practice out loud how to ask for a menu substitution.

To Do Before the Session:

- If possible, have the participant bring in menus from the restaurants he or she frequents.
- Get materials ready:
 - Sample menus from local restaurants.
 - Keeping Track book.
 - Pages for participant notebook.
- Optional handouts that are appropriate for the participant (for example, booklets on the nutrient content of fast foods).

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity? Try your action plan? What did you learn from the problem solving process?

Graph physical activity.

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Introduce the four keys to healthy eating out.

Today we're going to talk about eating out. **What kinds of places do you eat out at?**

Tailor the rest of the session to one or two of the places where the participant eats out most often. If the participant doesn't name several places or is not specific enough, prompt for a few of the following

examples: fast-food restaurants, other restaurants, church or community centers, cafeterias, friend's homes, snack bars or vending machines, in an airplane.

Do you find it difficult to stay under your fat gram goal when you eat out at these places?
What is difficult for you?

There are four basic keys to healthy eating out. *[First, indicate each of the major headings on the work sheet, as scripted below. Later you will come back to the specific points under each heading.]*

1. First, **plan ahead.** Having a plan will help you to anticipate difficult situations and handle them more easily. You won't run into so many surprises.
2. Second, **ask for what you want.** Be firm and friendly. We'll talk in a minute about how to do this so you won't offend anyone.
3. Third, **take charge of what's around you.** Take steps to make what's around you **support** you in your efforts to eat healthy. Get rid of the things that get in the way, if you can.
4. And finally, **choose foods carefully.**

Help the participant identify specific examples of how to apply the four principles.

Let's use **one of the places where you eat out as an example.**

What are some ways you can **plan ahead** for eating out at?

Follow along on the work sheet as you **discuss each of the four keys to healthy eating out as they apply to that type of restaurant.** Use some of the examples given below, but don't try to be exhaustive. Rather, choose those examples that relate to the specific difficulties faced by the participant. You may want to jot down on the work sheet a few strategies that are particularly relevant.

When you review **how to ask for what you want**, use the following script:

Many people find it hard at first to ask a waiter or waitress for something special. With practice, it gets easier. Here are some tips:

- **Begin with "I", not "You."**

"I would like," "I need," "I will have." Using "I" statements shows that you take responsibility for your own feelings and desires. "I would like my chicken broiled with lemon juice instead of gravy," or "I would like tossed salad instead of coleslaw, please."

"You should have," "you said," "you don't understand." Using "you" often puts others on the defensive. "You didn't put the salad dressing on the side!" Better: "I asked to have the salad dressing on the side, please."

- **Use a firm and friendly tone of voice that can be heard.**
- **Look the person in the eye.**
Eye contact says a lot. Avoiding eye contact often means you don't believe what you are saying.
- **Repeat your needs until you are heard. Keep your voice calm.**
Sometimes it may take several tries before you are understood. If you need to repeat yourself, keep your voice low but firm. A loud voice can be threatening to others.
Wishy-washy "Oh, well. I guess they couldn't broil the fish."
Threatening "You said you would broil my fish!"
Firm & friendly "This looks very nice. But I asked for my fish to be broiled, not fried. Would you have some broiled for me, please?"

When you review the fourth principle, **choose foods carefully**, have the participant:

- **Practice making a meal selection from an appropriate local menu.**
- **Practice out loud how they would ask for a menu substitution.**

Refer to menus from local restaurants and the "What's on the menu?" and "Fast food can be lower in fat" handouts for examples. It's important to role play aloud at this point to give the participant practice actually choosing words that are comfortable for him or her. At some point you may want to go to a restaurant with the participant and by ordering first, you can model how to make healthy meal selections and ask for menu substitutions. Participants may also need encouragement to ask family members to support them when they are at a restaurant, for example, to ask a spouse to say, "I'm glad you ordered milk for your coffee," instead of, "Are you sure you don't want cream?"

At fast-food restaurants

1. Plan ahead.

- Pick a restaurant carefully. Most fast-food restaurants now serve some low-fat foods, such as grilled chicken and salads with low-fat dressing.
- Plan what you will order without looking up at the menu. Menus can tempt you to order what you don't want.

2. Ask for what you want. Be firm and friendly.

- For example, "May I have my coffee with a little low-fat milk rather than cream, please?"
"Please leave the mayo off my burger."
- Ask how much is usually served. For example, "How many ounces is the hamburger, please?"

3. Take charge of what's around you.

- Be the first in your group to order. You won't be tempted by what or how much others order and they may follow your good example.

4. **Choose foods carefully.**

- Try grilled chicken sandwiches without special sauces or a salad with low-calorie dressing.
- Stay away from French fries. If you must have them, order a regular size (not a double) and Don't finish them all.
- If you must have a hamburger, order a regular size, without cheese, not a double or a cheeseburger.

At other restaurants (not fast-food)

1. **Plan ahead.**

- Pick the restaurant carefully. Go to one with low-fat choices. Call ahead to see what is on the menu. Stay away from "all you can eat" buffets, brunches, and happy hours.
- Eat less calories and fat during other meals that day or for a few days in advance.
- Have a little something to eat before you go to the restaurant so you're not too hungry when you get there. Eat fruit, some low-fat crackers, or drink water before you go out.
- Plan what to order without looking at the menu. Looking at the menu can tempt you to order more than you want.
- Don't drink alcohol before the meal. It may make it harder for you to follow your good intentions. Try tomato juice, club soda, or mineral water, instead.

2. **Ask for what you want. Be firm and friendly. Remember, you are paying for the meal. You have the right to ask for special services. And most restaurants want to make you happy.**

Ask for the foods you want:

- Ask for food substitutions. For example, catsup or mustard instead of mayonnaise on a sandwich. A tossed salad instead of coleslaw. Baked potato instead of French fries.
- Can foods be prepared in a different way? For example, ask that the fish be broiled and seasoned with lemon juice, not butter; ask that butter, margarine, and sauces be left off the vegetables.
- Don't be afraid to ask for foods that aren't on the menu. Many restaurants will prepare grilled meats, fish, and chicken without added fat or sauces, fresh fruit salads, and steamed vegetable platters with rice, even if they're not on the menu. Or look for foods on a different part of the menu (for example, if fresh fruit is on the breakfast menu, it may well be available as a dessert for dinner).

Ask for the amounts you want:

- Ask how much is usually served. For example, "How many ounces is the hamburger, please?"
- Ask for salad dressings, gravy, sauces, or spreads "on the side." For example, ask for dry toast with margarine on the side. Then use only a small amount. Or order salad dressing on the side, then limit the amount you use. (One idea is to dip your fork into the dressing before each bite.)
- Ask for less cheese or no cheese.

- Split a main dish or dessert with someone. Or order an appetizer as a main dish.
- Order a smaller size (appetizer, senior citizen's or children's portion, cup of soup).
- Before or after the meal, have the amount you don't want to eat put in a container or "doggie bag" to take home.

3. **Take charge of what's around you.**

- Be the first to order. You won't be tempted by what others order, and they may follow your good example.
- Keep foods off the table that you don't want to eat.
 - a. When a waiter or waitress brings rolls, chips, or other complimentary foods, say "No, thank you," and hand the food back right away.
 - b. When you order something, ask that half of it be put in a doggie bag **before** it's brought to the table. Then have it brought to you with the check.
- Ask that your plate be removed as soon as you are finished. You won't be tempted to eat more than you want while others finish their meals.
- Remove table tents from the table that advertise high-fat/calorie foods such as desserts.

4. **Choose foods carefully.**

- You can tell a lot from the words on a menu. Watch out for these high-fat words; look for these low-fat words, instead. [Refer to handout.]
- Watch out for sauces on meats, vegetables, and so on. Ask that these foods be served without the sauce.
- Think about how much food you really need. Do you need an appetizer? Bread? Make some compromises. "I'd rather have dessert so I'll skip the appetizer."
- Trim visible fat off meat.
- Take skin off chicken.

At another person's home or community center/potluck dinners

1. **Plan ahead.**

- Bring something from home for yourself and others. Examples: fruit salad, vegetable salad with low-calorie dressing.
- Talk to the host or hostess before you go, if you are comfortable doing so (particularly if you eat at their home often). Ask for their support in your efforts to lose weight.
- Eat a little something before you go, so you aren't too hungry when you arrive.

2. **Ask for what you want. Be firm and friendly.**

- Say "No, thank you. That looks lovely, though," when offered a food you'd rather not eat.

3. **Take charge of what's around you.**

- At buffets or cocktail parties, stay away from the buffet or appetizer table. Choose a small plate, and after serving yourself, sit at a table far away.

4. **Choose foods carefully.**

- Take only a small amount of high-fat/calorie foods, just enough to taste.
- Look at everything on the buffet before serving yourself. Then choose only 3 or 4 of your favorite foods, instead of trying a little of everything.

Airplanes

1. **Plan ahead.**

- Order a special menu ahead. Call 24 hours before departure. Many airlines have low-fat and vegetarian menus available.

2. **Take charge of what's around you.**

- Say "No, thank you," smile, and hand the peanuts right back to the flight attendant.

Banquets, Conferences

1. **Plan ahead.**

- Ask what is on the menu. Is anything prepared without fat?
- Order a special menu ahead. Even if the choices are limited, many caterers will prepare a steamed vegetable plate with rice and fruit salad upon request.

Assign home activity.

Describe a problem you have when you eat out. *[Record on the work sheet.]* Choose one of the four keys to healthy eating out that is likely to help you solve the problem and that you can do. Make a positive action plan. *[Complete the work sheet with the participant.]*

For next week:

- **Keep track** of your weight, eating and activity.
- **Try your action plan.** And before you come to the next session, answer the two questions on the bottom of the work sheet (Did it work? If not, what went wrong?).
- For participants who eat out often, ask the participant to collect menus for restaurants the participant frequents and bring them in to the next session.

Any questions?

Session 11: Talk Back to Negative Thoughts

Objectives:

In this session, the participant will:

- Recognize that everyone has negative thoughts and identify examples of them.
- Learn how to stop negative thoughts and talk back to them with positive ones.
- Practice stopping negative thoughts and talking back to them with positive ones.

To Do Before the Session:

Get materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Optional handouts that are appropriate for the participant (for example, a Stop! Sign prop to hold up when you hear the participant expressing a negative thought).

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity? Try your action plan? What did you learn last week about healthy eating out?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Graph physical activity.

If the participant has brought in restaurant menus, help the participant practice ordering from the menus.

Help the participant identify examples of negative thoughts.

Today we're going to talk about stopping negative thoughts.

Everyone has negative thoughts at times. These negative thoughts can lead you to overeat or be inactive. Then afterwards you may feel even worse about yourself. A vicious cycle of self-defeat can result.

For example, suppose you came home after a hard day at work. You think to yourself, "I'm tired of working so hard. I'm sick of being in this study. I can never eat what I want." This negative thought might lead you to eat some potato chips. And then you think, "I did it again. I'll never lose weight." Next, you're discouraged and go on to eat more of them.

Sometimes we aren't aware we are having negative thoughts. Negative thinking becomes such a habit for most of us that we tend to believe and act on our negative thoughts without even hearing them.

The goal of this session is to help you hear your negative thoughts and teach you to talk back to them.

Here are some common examples of negative thoughts.

Review each category and the example(s) on the work sheet, then ask a question or two to get the participant thinking about his or her own experience with negative thoughts.

1. Good or Bad Thoughts.

These thoughts divide the world into:

- Good and bad foods;
- Seeing yourself as a success or failure;
- Being on or off the program.

Sometimes this is called "all or nothing" or "light bulb" thinking (either on or off) with nothing in between.

Example: "Look at what I did. I ate that cake. I'll never be able to succeed."

- Do you have some foods you consider "good," and some foods you consider "bad?"
- What happens when you eat a little of what you consider to be a "bad" food?
- Can you think of some problems with considering a food "bad?"

2. **Excuses (or Rationalizations)**

These thoughts **blame something or someone else for our problems**. We act as if they have so much power that we have no choice but to overeat or be inactive.

We don't mean to go off the program, but we "can't help it."

Example: "I don't have the will power."
"I have to buy these cookies just in case company drops in."

- Can you think of a time when you bought some high-fat/calorie food "for someone else"? Did they really need the food, or do you think you used them as an excuse to buy the food for yourself?

3. **Should Thoughts.**

These thoughts **expect perfection**. Of course, no one is perfect, so SHOULD thoughts are a **set-up for disappointment**. They also **lead to anger and resentment** because "should" assumes that someone is standing over us, forcing us to do what we don't want to do.

Example: "I should have eaten less of that dessert."

- What kind of things do you think you "should" or "should not" do to lose weight and be more active?
- What do you expect yourself to do perfectly (for example, self-monitoring)? What happens when you expect perfection of yourself? How do you feel? How does it affect your future decisions and choices?

4. **Not As Good As Thoughts.**

These thoughts **compare us to someone else** and then **blame ourselves for not measuring up**.

Example: "Mary lost two pounds this week, and I only lose one."

- Do you compare yourself to someone else? Who?
- How does comparing yourself to that person affect you? How does it make you feel? How does it affect your decisions and choices about eating and being active?

5. **Give Up Thoughts.**

These thoughts **defeat us**. They **often follow the other kinds of negative thoughts**.

Example: "This program is too hard. I might as well give up."

- Do you ever want something good to eat and think, "I'm sick of this Lifestyle Balance program"?

Explain how to talk back to a negative thought.

Once you are aware of a negative thought, you can "talk back to it." Here's how:

1. First, **catch yourself** having the negative thought. Ask yourself, "Is this thought moving me forward or bringing me down?" As soon as you're aware of a negative thought, say to yourself, **"I'm doing it to myself."**
2. Then **imagine shouting "STOP!" to yourself.** Picture a **huge, red stop sign.** *[You may want to hold up the STOP! sign prop at this point.]* The stop sign is so big that it takes up all the room in your mind. This should startle you and get rid of the negative thought.
3. **Talk back with a positive thought.** No matter how effectively you've stopped a negative thought, it will probably return again in a similar situation because it has become a habit for you. So it's important to **begin to build a new habit: positive thinking.** After you stop a negative thought, talk back to it with a positive one.

Review the categories and the examples on the work sheet, making the following points.

- **Good or Bad:** Talk back with **Work Toward Balance.**
Don't expect perfection of yourself, but don't indulge yourself either. Work toward an **overall balance.**
- **Excuses:** Talk back with **It's Worth a Try.**
Instead of looking for something or someone else to blame, why not give yourself a chance? Try something. You just might succeed.
- **Should:** Talk back with **It's My Choice.**
You are in charge of your eating and activity. No one else is responsible for your choices or standing over you with unrealistic expectations.
- **Not As Good As:** Talk back with **Everyone's Different.**
- **Give Up:** Talk back with **One Step at a Time.**
Problem solving is a process. It takes time to make life-long changes. Learn from what doesn't work and try another option. Learning is always a success.

Now let's **practice** stopping negative thoughts and talking back with positive thoughts.

Look back over the kinds of negative thoughts we've discussed. What kind are most familiar to you? For example, do you tend to make excuses or are you more likely to compare yourself to someone else? What are some examples?

Write examples of negative thoughts on the work sheet. If the participant doesn't name examples, use several from the previous pages.

Now let's take them one at a time. First, say the negative thought out loud. Then say "Stop!" And then talk back to it out loud with a positive thought.

Use the remaining time in the session to actually role-play this with the participant. Use a stop sign prop if you find it helpful. Record the positive thoughts on the work sheet.

This session may be an appropriate time to review with participants the work sheet "Remember Your Purpose" (Session 1) on which they recorded their personal reasons for joining the study and so on. Details from this work sheet may provide images and words for the participant to use in talking back to negative thoughts with positive ones. Any imagery that is significant to the participant may help make the process of "talking back" more meaningful and fun; for example, a participant might find it enjoyable to imagine a devil on one shoulder and an angel on the other, and to see the task of positive thinking as, "letting the angel talk."

Assign home activity.

For next week:

- Keep track of your eating and activity.
- Catch yourself thinking negative thoughts. Write them in your Keeping Track books.
- Practice stopping them and talking back to them with positive thoughts.

Next week we'll talk about how you did.

Any questions?

During this session, some participants may raise problems outside the expertise of the Lifestyle Coach, such as a significant clinical depression, anxiety, or a clinical eating disorder.

Session 12: The Slippery Slope of Lifestyle Change

Objectives:

In this session, the participant will:

- Review the participant's progress since Session 7 or 8 ("Tip the Calorie Balance").
- Identify some things that cause the participant to slip from healthy eating or being active.
- Discuss what to do after a slip to "get back on your feet again."

To Do Before the Session

Review the participant's progress. Note any plans that were made to improve weight loss and activity level, which strategies were used, and which were successful or unsuccessful. If the participant is not currently at goal for weight loss and/or activity, refer to the Tool Box for ideas of additional strategies required or optional for particular problems.

If you have copies of some of the participant's past Keeping Track records, review them as well. Note some of the positive changes the participant has made.

Make sure the participant's How Am I Doing? graphs for weight and activity are up to date.

Have materials ready:

- Keeping Track book.
- Pages for the participant notebook.
- Meal plans appropriate for the participant's calorie goal. Tailor to the participant's food preferences as much as possible before the session.

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity? What negative thoughts did you catch yourself thinking? Were you able to stop them and talk back with positive thoughts?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Graph physical activity.

Review the participant's progress since Session 7 or 8, and if not at goal, develop an action plan to improve progress in reaching weight loss and activity goals.

Today we're going to talk about what are called "slips," or times when you don't follow your plans for healthy eating or being active.

Let's use skiing as an example. Everyone who learns to ski knows that they will "slip" and fall down. It's a natural part of learning to ski. What a skiing instructor does is to help beginning skiers anticipate when they might fall down and show them how to get up again. That's what we'll do today--talk about when you might "slip" from your eating and activity plans, and how you can get back on track again after you slip.

Note: Throughout this session, try to use analogies in addition to skiing that are meaningful to the participant. (For example, one analogy is how we handle fires. First, we try to identify high-risk situations in which fires are likely to occur. Second, we try to take steps to avoid these situations if we can. Third, in case a fire does occur, we plan ahead for a way to put out the fire and/or escape.

We make a plan that is as simple and easy to remember as possible so that we are more likely to follow it while under stress.) You will also want to use a meaningful analogy for how the participant has developed other skills by making mistakes and learning from them, such as learning to drive a car, bake a cake, and so on.

Before we talk about slips, we'll take some time to review your progress

- **What are some of the major changes you've made to be more active?** Include both what you do to reach your goal (that is, those activities you record) and what you do to be more active in general **What changes have you made to eat less fat (and fewer calories)?** Briefly record on the work sheet some of the changes made by the participant. Praise and encourage the maintenance of these changes.

Have you reached your weight goal? Your activity goal?

Refer to the How Am I Doing? graphs for weight and activity, and check yes or no on the worksheet.

If the participant is **at goal** for weight loss and activity, praise the progress made.

If the participant is **not at goal** for weight loss or activity, praise whatever progress has been made. Encourage the participant to improve, and develop a related plan using the work sheet. **Follow the guidelines in the Tool Box as to which strategies are required to address particular problems identified.** For example, some participants may need to be given meal plans at a lower calorie level.

Define slips.

Now let's move on to the topic for today, "**slips.**"

Slips are times when you don't follow your plans for healthy eating or being active.

Slips are:

- **A normal part of lifestyle change.** Just like falling down is a normal part of skiing. If you are going to ski, you are going to fall. All skiers will fall. And everyone who sets out to lose weight and be more active will have slips.
- **To be expected.** If you haven't already had some slips, you most certainly will have them in the future. Slips are **inevitable.**

Does this sound discouraging? Well, it doesn't have to be. Because **slips don't hurt your progress. What hurts your progress is the way you react to slips.** So today we'll talk about the best way to react to slips when they happen.

Identify some things that cause the participant to slip from healthy eating or being active.

Different people have different things that cause them to slip. For example, **moods or feelings** cause many people to slip from healthy eating.

Some of us tend to overeat when we're **happy**. Imagine that:

Your **family is celebrating**. Maybe it's a holiday, a birthday, or a vacation. There is plenty of everyone's favorite foods, from appetizers to desserts. And for years, your family's custom has been to "take it easy," have fun and just relax during these times. **What would this situation be like for you? Would you tend to slip in this kind of situation?**

Some of us are more vulnerable to overeating when we're **bored**. Imagine that:

You're **at home alone, watching a favorite TV program**. You're feeling okay, pretty relaxed, but a little bored. A commercial comes on at the end of the program, and you find yourself wandering into the kitchen. **What would this be like for you?**

Other people overeat when **upset**. Imagine that:

You are settling down for a relaxing evening at home. Someone in your family starts to talk about something that's been part of an **ongoing argument** between the two of you. You both get angry and he or she stomps out of the house, slamming the door. You head for the kitchen. **What would this situation be like for you?**

Or here's another example:

You're **behind on a project at work**. The boss has been looking in on you every 10 minutes and glaring at you impatiently. You feel pressured and very tense. You go get yourself a cup of coffee and see a delicious snack that someone brought in that morning. **What would this be like for you?**

Which is the most difficult for you in terms of slipping from healthy eating: feeling happy, bored, or upset? *[Record on the work sheet.]* **Are there other things that cause you to slip from healthy eating?**

Give the participant time to name a few examples. Record on the work sheet.

What things cause you to slip from being active?

Have the participant name several examples, such as vacations, holidays, feelings or moods, cold or hot weather.

The situations that lead to slips differ from person to person. For example, you may tend to eat when you're bored, whereas someone else may get involved in a hobby. Or when you are at a party, you may be so busy talking and laughing that you forget to eat, whereas someone else may find the goodies are just too tempting. **What causes you to slip is learned. It is a habit.**

The way you react to slips is also a habit. You can learn a new way to react to slips that will get you back on your feet again.

Discuss what to do after a slip to get back on your feet again.

First, **remember two things:**

- **Slips are normal and to be expected.** 99.99% of all people who are on their way to losing weight and being more active have slips. But a slip doesn't need to lead to giving up completely. Slips can and should be useful learning experiences.
- **No one time of overeating or not being active, no matter how extreme, will ruin everything.** You won't gain more than a few pounds of weight even after the biggest eating binge imaginable--unless you stay off track and keep overeating time and time again. **The slip is not the problem. The problem occurs if you don't get back on your feet again and keep going toward your goals.**

So after you have a slip:

1. **Talk back to negative thoughts with positive thoughts.**

The negative thoughts that come after a slip can be your worst enemy. They can lead to feeling discouraged, guilty and angry and undermine your ability to handle the slip effectively. Talk back to the negative thoughts with positive ones. "I am not a failure because I have slipped. I can get back on my feet again."

2. Next, **ask yourself what happened.**

Use the opportunity to look closely at the situation and ask yourself what happened. Was it a special occasion? If so, is it likely to happen again soon? Did you overeat because you were lonely, bored, or depressed? Did you eat because of social pressure? Did you skip activity because you were too busy with other things, or because of work and family pressures? Use these questions to review the situation and think about it objectively.

Learn from the slip.

Then you can plan a strategy for handling the situation better next time. **Can you avoid this situation in the future** (for example, by not sitting near the food or by not wheeling past the candy machine)? If you can't avoid it, **can you manage it in a better way** (for example, by making sure you have low-calorie foods available at home)?

3. **Regain control the very next time you can.**

Do **not** tell yourself, "Well, I blew it for the day," and wait until the next day to start following your eating plan. **Make your very next meal a healthy one. Get back on schedule with your activity plan right away.** You will not have set yourself back very much if you follow this suggestion.

4. **Talk to someone supportive.** ("Talk it through, don't eat it through.")

Call your lifestyle coach or someone else on staff. Call another participant or another friend. Discuss your new strategy for handling slips. Commit yourself to renewed effort.

5. Finally, **focus on all of the positive changes you have made** and realize that you can get back on track. The same person who "blew it" today is the same person who has been successful during many previous weeks. Slips do not reveal the "real you" (hopeless, lacking willpower, etc.). They are simply another occasion of behavior. **Remember, you are making life-long changes. Slips are just one part of the process.**

Assign home activity.

Describe one thing that has caused you to slip from healthy eating.

Could you **avoid it** in the future? If so, how? *[Record on the work sheet.]*

If not, make a plan for **how to get back on your feet** the next time you slip. *[Record.]*

Describe one thing that has caused you to slip from being active.

Could you **avoid it** in the future? If so, how? *[Record on the work sheet.]*

If not, make a plan for **how to get back on your feet** the next time you slip. *[Record.]*

For next week: a) Keep track of your eating and activity. b) Try your two action plans.

c) Answer the questions on the work sheet.

Any questions?

Session 13: Jump Start Your Activity Plan

Objectives:

In this session, the participant will:

- Discuss ways to add interest and variety to the participant's activity plans.
- Learn the definition of "aerobic fitness."
- Learn the F.I.T.T. Principles (frequency, intensity, time, and type of activity) as related to heart (aerobic) fitness.

To Do Before the Session:

Have materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Optional handouts that are appropriate for the participant (for example, on various barriers to physical activity).

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity?

Did you try your two action plans to get back on your feet after slipping? How did it go?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Graph physical activity.

Discuss ways to add interest and variety to the participant's activity routine.

So far in the Lifestyle Balance program, our focus in terms of physical activity has been on increasing the amount of time you are active. We've moved gradually from 30minutes per week to 2 ½ hours per week of new physical activity. By this time in the program, many participants find that their activity routine has become a little stale and boring. **Boredom is a problem because it may cause you to slip back into old habits of not being active.** So it's important to be aware of

any boredom you're feeling about your activity plan, and do something to keep it fresh and interesting.

That's what we'll talk about today--**ways to "jump start" your activity routine** (or give it new energy when it's becoming a little too "routine").

First, **add variety**.

- **Do something new and different** now and then. Don't expect yourself to do the same activity, day in and day out, every season of the year, any more than you would expect yourself to eat the same food, day in and day out, all year long. Remember, you are making life-long changes, and being active is something you will be doing for the rest of your life. So build in some variety. For example, if you usually do aerobic conditioning during the week, strength (resistance) training on the weekend.

Can you think of some ways to vary what you do for activity?

Record on the work sheet. Include lifestyle activity but be sure the participant understands to self-monitor only the physical activities that are similar (or higher in) intensity (refer to Manual of Operations).

If the participant expresses interest in learning more about a particular activity, such as strength(resistance) training, consider making an appointment for the participant to meet with the exercise specialist on staff for instruction.

Do the same activity in a new place. For example:

- Wheel on a different path through the park.
- Wheel in a different neighborhood after work.

What are some ways you can vary where you do your activity? (*Record.*)

Be active as a way to be social.

- Instead of going out for a cup of coffee, go out for a "wheel and talk" with a friend or family member.
- Plan a weekend hike with a group of friends.
- Go wheeling with a club.
- Join a basketball team.
- Sign up with a group of friends for a wheel for charity.

What are some activities you could do with a friend, family member, or group as a way to socialize? (*Record.*)

It also helps if you **make being active fun**.

- Some people enjoy listening to a radio, music tapes or books on tape while they exercise
- Plan tours of cities when you travel.

What would be fun for you? (*Record.*)

Another way to prevent boredom is to **challenge yourself**.

- Prepare yourself for a race.
- Set up a friendly competition with a friend (whoever wheels the most miles before a certain date gets taken out to lunch by the other).

What would make activity more challenging for you? (*Record.*)

Have you been bored at times with your activity in the past?

Have you found anything to be particularly helpful for you at those times?

If you're not bored now, please be sure to bring it up whenever you do feel bored in the future. Use me and our activity specialist as resources to help you. For example, we can talk about some community programs that might add interest to your activity routine, and so on.

Define "aerobic fitness."

One way to add something new to your activity routine is to begin to focus on **improving your "aerobic fitness."**

"Aerobic fitness" refers to **how well your heart can pump oxygen ("aer-")** through your blood to your muscles in your body.

Your heart is a muscle, too. If you exercise your heart (make it beat faster), it will become stronger over time. This is just like the muscles in your arm becoming stronger if you lift weights every day.

As your heart becomes stronger, you'll notice that it's easier for you to do things like wheeling up inclines and carrying groceries.

Explain the F.I.T.T. Principles.

Not all ways of being active will help strengthen your heart--only those that are "F.I.T.T."

This is what "F.I.T.T." stands for:

"F" stands for **frequency**, or **how often you are active**.

Aerobic fitness levels go down within 48 hours of no activity, so it's important to be active often.

- Try to be active on most days of the week (at least 3 days per week is recommended; 5 to 7 days are even better).
- To avoid soreness and injury, it's best to **increase the frequency slowly**.

"I" stands for **intensity**, or **how hard you are working while being active**.

This is usually measured by **how fast your heart beats**. We want your heart to beat faster than it usually does, so that it will become stronger, but we don't want it to beat so fast that you could injure yourself.

- The goal is to stay within what's call your "target heart rate", about 50-70 % of the maximum number of times your heart can beat in a minute for someone your age.

Here is how to **figure your target heart rate**.

Review the formula on the work sheet and calculate the participant's own target heart rate.

Have you ever taken your heart rate or pulse?

Review with the participant the steps for taking your heart rate as described on the work sheet. Use a pen or marker to mark on the participant's wrist exactly where he or she is able to find the pulse. This will help the participant find it quickly when exercising.

- Another way to get a rough idea of how hard you should be working is to **breathe fast enough that you can talk but not sing**. You should be able to have a conversation with a friend while exercising, but **if you can break into song, speed it up!**

On the other hand, **if you have trouble breathing and talking while you exercise, slow down**.

- **As you do regular physical activity over time, your heart doesn't beat as fast** as it used to. For example, you'll notice that your heart doesn't beat as fast when you wheel up an incline, and you don't get as out of breath.

This means that you are becoming more fit, that your heart is doing the same amount of work with less effort. It also means that to continue strengthening your heart, **you will need gradually to do more challenging activity to reach your target heart rate**. For example, you'll need to exercise more intensely than you used to get the same benefit in terms of aerobic fitness.

"T" stands for **time**, or **how long you are active**.

- To improve your aerobic fitness, you should **stay active continuously for at least 10 minutes**. That's why we don't ask you to record in your Keeping Track any activity that doesn't last at least 10 minutes.
- We recommend that you **slowly increase the time you are active to 20 to 60 minutes**.
- The **total number of minutes per week should at least equal your Lifestyle Balance activity goal for that week**.

The final "T" stands for **type of activity**.

- To improve your fitness, you should do "**aerobic**" activities. As we said before, these are activities that **challenge your heart**. Brisk exercise will result in aerobic activities.
- These activities **use large muscle groups** and
- **Last 10 minutes or longer**. Brief activities that don't require your heart to work harder, such as bowling, pitching a softball, or washing a window, will not improve your aerobic fitness.

Introduce another way to measure exercise intensity.

Measuring your heart rate is one way to keep track of your intensity (or how hard you are working) when you're active. But even without measuring their heart rate, most people have a good sense of how hard they're working when they're active, just by listening to their body.

Rate yourself on this scale while you're being active. How hard are you working?

Review the work sheet with the participant. For your own background information as a Lifestyle Coach, the scale is based on Borg's original Rating of Perceived Exertion (RPE) Scale which is a numerical scale from 6 to 19, with 7 corresponding to very, very light, 9 to very light, 11 to fairly light, 13 to somewhat hard, 15 to hard, 17 to very hard, and 19 to very, very hard. The original scale was designed to approximate what one would estimate the corresponding heart rate to be, by adding a zero to the end of the RPE. For example, an RPE of 13 (somewhat hard) would approximate a heart rate of 130. So if a participant calculated her upper heart rate limit to be 130, her upper RPE limit would be around 13.

Assign home activity.

For next week:

- Keep track of your weight, eating and activity.
- Do your best to reach your activity goal for the week. *[Record.]*
- Take your heart rate or pulse every time you're doing physical activity.
- Adjust how hard you are working during an activity so that you stay within your target heart rate *[specify]* or keep how hard you are working at this level *[specify]*.

Any questions?

You may want to ask the participant to invite a family member to the next session, Make Social Cues Work for You, if you and the participant think that would be helpful in planning strategies for handling social cues.

Session 14:

Make Social Cues Work for You

Objectives:

In this session, the participant will:

- Review examples of problem social cues and helpful social cues.
- Discuss ways to change problem social cues and add helpful ones.
- Review strategies for coping with social events such as parties, vacations, having visitors, and holidays.
- Make an action plan to change a problem social cue and add a helpful one.

To Do Before the Session:

Ask the participant to invite a family member to this session if you and the participant think that would be helpful in planning strategies for handling social cues.

Have materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Optional handouts that are appropriate for the participant (for example, with tips for handling parties, holidays, vacations, and other social events; low-fat/calorie recipes for entertaining; helpful ideas for low-fat eating and staying active while traveling).

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity?

What was it like taking your pulse or **heart rate**? Were you able to stay within your target heart rate?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Graph physical activity.

Review the concept of food and activity “cues” and define social cues.

In an earlier session we talked about **how to “take charge of what’s around you.”** We took an imaginary video camera through your house and where you work, and we looked for problem food or activity “cues,” things that would prompt you to think about eating or to be inactive, like a TV set or a bag of cookies on a kitchen counter. We planned some ways to get rid of problem cues and add positive cues (for example, watch less TV, keep high-fat foods out of the house).

In that session we focused on the sight and smell of food or certain activities that make you think about food. Today we’re going to talk about **social cues**, or **what other people say or do that affects your eating and activity**. Again, we will plan some ways to **reduce problem social cues** and some ways to **add positive ones**.

Give examples of problem social cues and positive social cues.

Problem Social Cues

One of the most powerful **problem social cues** is:

- **The sight of other people eating problem foods or being inactive** (for example, you go to a bar where you see other people eating potato chips and watching TV). Can you think of an example in your own life? Is it difficult for you when you see someone in your family or a friend eat certain foods? (Record examples briefly on the work sheet.)
- **Being offered (or pressured to eat) problem foods or being invited to do something inactive** are also negative cues (for example, your spouse buys you candy for your birthday or a friend asks you to come over to watch football). What are some examples in your own life?
- **Being nagged** is a negative cue (for example, your spouse says, “You shouldn’t be eating that bacon. It’s too high in fat.”). Some people may think that nagging is helpful, but actually it tends to cause the behavior it’s designed to stop. Does anyone nag you about your eating or activity?
- **Hearing complaints** is a negative cue, too (for example, your daughter says, “I hate this frozen yogurt. Real ice cream is better,” or your spouse says, “You’re always outside exercising. You don’t have any time for your family any more.”).

Do you hear complaints from anyone about your eating or activity?

Now let’s compare problem social cues with **positive social cues**.

Positive social cues include:

- The **sight of other people eating healthy foods or being active** (for example, you go out to dinner with another participant who orders low-fat foods or you go to an aerobics class). Can you think of any people who are good examples for you? In what way? (Record on the work sheet.)

- **Being offered healthy foods or being invited to do something active** (for example, your mother offers you fruit salad for dessert or asks you to go for a wheel). Does anyone do this for you?
- **Being praised** (for example, your spouse says, “The oatmeal was delicious this morning, honey.”). Who praises you for your efforts and accomplishments?
- **Hearing compliments** (for example, your daughter says, “Thanks for buying frozen yogurt, Mom. It’s a lot healthier than ice cream,” or your spouse says, “You’re really committed to exercising every day. I’m proud of you.”). Does anyone compliment you?

When you respond to a social cue in the same way over and over again, you build a habit.

The cue becomes paired with the way you respond, and your response becomes more and more automatic. In an earlier session, we used the example of eating popcorn whenever you go to the movies as a food cue that over time becomes a habit for many people. It works the same way with social cues.

Let’s say that since childhood, your mother has offered you second helpings of food at the dinner table. You developed a habit of accepting her offer. Now when you return home as an adult and your mother offers you second helpings, it is hard for you to refuse.

It’s important to understand that with social cues, the **other person has also learned a habit**. So in the example we’ve just used, your mother has learned to offer you second helpings and expects that you will accept the offer. **This makes social cues even harder to change than other cues.**

Discuss ways to change problem social cues.

How can you change problem social cues?

1. As with problem food cues, one of the best things you can do is to **stay away from the cue, if you can**. For example:
 - Move to a different room if a family member eats problem foods in front of you.
 - Skip certain parties that are just too tempting for you.
 - Socialize with people by going bowling, dancing, or to the movies. Don’t go out to eat as a way to socialize.
 - Change the subject when someone starts talking about food or your weight or activity.
2. **Change the cue, if you can**. This means trying to influence the other person’s habit, if you can. For example, when someone nags, complains, eats problem foods in front of you, or pressures you to eat:
 - **Discuss the problem. Brainstorm options**. For example, “It’s hard for me when you eat ice cream in front of me. It really tempting. Is there away we could get together and have fun, but not eat ice cream?” **Be willing to compromise** to find a solution that will work for everyone.

- **Tell people about the study, your efforts to lose weight and be more active, and why this is important to you.** Many people will be willing to help if they understand that you are trying to change your eating and activity and why.
- **Ask others to praise you for your efforts and ignore your slips. This is KEY to your success.** Explain to your friends and family that this is what would be most helpful to you. In turn, be sure to thank them when they notice your efforts and overlook your slips.

(Role play this with the participant, using an example that is meaningful to him or her.)

3. If you can't stay away from the problem social cue or change it, **practice responding in a more healthy way.** Over time you will **build a new, healthier habit** and **the other person will learn a new habit, too**, because of your new response. For example:

- **Say "No" to food offers.** If you are consistent and continue to say "No," others will eventually stop offering.
- One of the most important things you can do is to **show others you know they mean well, and suggest something they can do to help you. Be specific.** Most people mean well when they nag, offer food or pressure someone to eat (for example, many people think that being a good hostess means insisting that guests have second helpings). If you recognize that they mean well and give them a specific, positive alternative, they can still feel helpful and you are more likely to reach your goals, too. For example, when a hostess offers you second helpings, say, "Thanks so much for offering. You know what I'd really enjoy is some coffee." **If you can, give them specific ideas of how to help ahead of time**, before you are confronted by a challenging situation.

Role play saying "No" to food offers, using an example that is meaningful to the participant.

Illustrate that the participant should be prepared to say "No" several times to someone who continues to offer, e.g., "Are you sure you don't want a piece of cake?"

Remember that **it takes time to break an old habit or build a new one.** Change doesn't happen overnight. And with social cues, there are at least two people involved in making a change: yourself and someone else. **Don't expect other people to adjust instantly** to a new way of relating, any more than you expect yourself to change instantly.

Discuss ways to add positive social cues.

Not all social cues are problems. You can use social cues to *help* you eat healthier and be more active. For example:

- **Spend time with people who are active and make healthy food choices.** For example, at parties stand next to people who spend most of their time talking and dancing instead of eating.
- **Put yourself in places where people are active.** For example, join an exercise club or sports league. Come to the study activity sessions.

- **Set up a regular “date” with others to be active.** You will be more likely to be active because you won’t want to disappoint them by cancelling.
- **Ask your friends to call you to remind you to be active or to set up dates to be active.**
- **Bring a low-fat/calorie food to share.** For example, bring a fruit salad to a potluck dinner.
- **Be the first to order when you eat out at a restaurant** and order healthy foods. This is much easier than waiting until after others order high-fat foods and then trying to make a healthier choice. In addition, you will provide a positive social cue for other people.
- **Be social by doing something active.** For example, exercise and talk. Go out dancing instead of going out to dinner. Start a family tradition of going for exercise after dinner instead of watching TV.

An important way to change negative social cues and add positive ones is to **ask people who want to support you for help.**

What people in your life want to support you? *[Record a few names.]*

What could they do to help you? Here are some ideas. Would any of these be helpful to you?

Review the ideas on the work sheet. Check a few that the participant thinks would be helpful.

Add other ideas at the bottom of the chart. Some participants may want to copy the work sheet to give to a supportive friend or family member.

Discuss ways to handle social events such as parties, having visitors, or holidays.

Social cues are especially powerful at social events such as parties, holidays, vacations, and when you have guests in your home or are a guest in someone else’s home. These events:

- **Upset our routine** (for example, you usually exercise after dinner, so how do you fit exercising in on a day when you’re going to a party after dinner?),
- **Challenge us with unique food and social cues** (for example, your family serves appetizers whenever there are guests in the house but not at other times; you go on vacation to a place you’ve never been before and you’re not familiar with any of the restaurants),
- **May involve habits that have developed over many years and so can be very powerful** (for example, for the past 30 years on Thanksgiving, your family has watched the parade on TV and had pumpkin pie with whipped cream for dessert).

What are some social events that are difficult for you?

Get an idea of the kind of social events the participant attends. If it is near a holiday or vacation, you may want to focus during the remainder of the session on brainstorming options and making an action plan for that specific event. Optional participant handouts (see Appendix) are available that provide guidelines for holidays, parties, vacations, and so on.

To handle social events well, try to anticipate the problems that will occur. What exactly might be difficult for you? Then brainstorm your options ahead of time. Here are some ideas: *[review the examples on the work sheet]*:

- **Plan ahead.**
- **Stay away from problem cues when you can.**
- **Change problem cues.**
- **Respond to problem cues in a more healthy way.**
- **Add helpful social cues.**

Stay positive. Think of every social event as an opportunity to learn what works well for you and what doesn't. Remember, you are building healthy habits for a lifetime.

For participants that entertain, you may want to distribute some low-fat/calorie ideas and/or recipes (for example, recipes for low-fat dips and a list of low-fat crackers). Participants who travel often may appreciate the optional handout on helpful ideas for low-fat eating and staying active while traveling.

Assign home activity.

With the participant, develop and record on the work sheet two action plans to:

- Change a problem social cue.
- Add a helpful social cue.

If it is near a holiday, vacation, or particular social event, include an action plan for that event.

Assign home activity.

This week:

- Keep track of your weight, eating and activity.
- Try your two action plans for making social cues work for you.

And before the next session, answer the questions (Did it work? If not, what went wrong?) for both action plans

Session 15: You Can Manage Stress

Objectives:

In this session, the participant will:

- Discuss how to prevent stress and cope with unavoidable stress.
- Discuss how study participation can be a source of stress and how to manage that stress.

To Do Before the Session:

Have materials ready:

- Keeping Track book.
- Pages for participant notebook.

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity?

Were you able to follow your action plans (change the problem social cue and add the helpful one)?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Graph physical activity.

Define stress and its relevance to the study.

Stress is tension or pressure. Stress is a natural part of living our life.

Any change, good or bad, big or small, can cause stress. Big changes or events in our life--like getting married, a serious illness, changing jobs--can cause stress. Small events- like losing your keys, having a birthday, having a flat tire, or needing to get your errands done before picking up your children--can also cause stress.

What kinds of things make you feel stressed?

Why are we talking about stress in the Lifestyle Balance program? Because **many people react to stress by changing their eating and activity habits**. Some people eat and drink too much as a way to deal with stress. Others may stop eating. Some people become very inactive and withdrawn.

What is it like for you when you get stressed?

If the participant does not provide examples, mention one or two situations that are typically stressful (such as being under a deadline at work, illness, being faced with unexpected responsibilities such as a sick child or car repair). Ask how the participant feels or reacts. Based on the response, point out any physical and emotional symptoms (headache or muscle tension) and behavioral changes that might affect eating and activity.

- Do you get any physical symptoms like a headache or stomach ache or muscle tension?
- Do you change your behaviors when you feel stressed?
- Do you eat more when you are stressed?
- Do you change the kinds of food you eat?
- Do you change how active you are or the kind of physical activities you do?

Discuss ways to prevent stress.

An ounce of prevention is worth a pound of cure, and this is certainly true when it comes to stress. The best approach is to **prevent stress whenever you can**. Here are some ideas:

1. Practice saying, “No.”

Practice saying “No” when someone else asks you to do something you don’t want to do. Say “Yes” only when it is important to **you**.

Saying “No” can be hard. It causes some tension or stress. But that stress is usually short-lived. If you say “Yes,” you may have hours, weeks, or months of stress as you do whatever you agreed to do.

2. Share some of your work with others, both at home and at work.

Delegate what you can to someone else. For example, your spouse and children might be able to help clean the house, cut the lawn, shop for food, prepare meals, and do laundry. A co-worker might be able to help you with an overwhelming project at work.

Sharing work doesn’t mean you’re being irresponsible. Giving responsibility to others, even if they aren’t as experienced as you, gives them a chance to learn, participate, and gain experience. One warning: Don’t expect them to be perfect. Criticizing the efforts of others who are trying to help can

be another source of stress. Instead, support them for their efforts and be patient as they gain skills.

3. **Set goals you can reach.**

Sometimes we create our own stress by trying to be perfect. If you set reasonable goals, you are more likely to succeed. When you succeed, you are less likely to feel stressed. Remember, we talked about this when we discussed negative thoughts—if you try to be perfect, you probably won't succeed!

Periodically, take a good look at the demands you are placing on yourself. Ask yourself, "Am I expecting myself to do more than anyone could possibly do?"

4. **Take charge of your time.**

Make schedules with the real world in mind. Don't try to accomplish in 30 minutes what realistically will take an hour. Take a good look at your to-do list, eliminate what isn't essential, and give yourself a realistic amount of time to accomplish the rest.

Get organized. Chaos is very stressful. It's also inefficient. Devote some time every day to getting organized, and you will save time and stress in the long run.

5. **Use the steps for solving problems.**

If changing your eating and activity habits is causing stress, take action. Use the steps to solving a problem that we discussed in an earlier session:

- Describe the problem in detail. Discuss it with your family or friends if they are involved.
- Brainstorm your options.
- Pick one option that is very likely to work and that you can do.
- Make an action plan.
- Then try it and see how it works.

Continue the process until you find a solution. Sitting on problems can cause even more stress. Solve them instead and move on.

6. **Plan ahead.**

Think about what kind of situations are stressful for you. These are times when you are at high risk, so plan ahead for how to handle them or work around them. For example, are holidays especially stressful for you? If so, plan some ways to make your life easier during the holidays. Examples: Buy frozen meals to have on hand for busy days. Decide what parts of decorating the house are not essential to you and spend that time relaxing instead.

7. **Keep things in perspective. Remember your purpose.**

Maintain a positive attitude. Think of all the good things in your life. And remember why you joined the study.

8. **Reach out to people.**

Think about who you can turn to for support. **Ask supportive people to help** when you are overwhelmed or need someone to encourage you. We talked about this last week.

9. **Be physically active.**

Many people find that being active helps them cope with stress and feel more relaxed and able to manage stressful situations more smoothly.

Discuss ways to cope with unavoidable stress.

What about the times when you can't avoid stress?

- **First, catch yourself feeling stressed as early as you can.**

We talked before about action or behavior chains and that it's important to try to break them as early as possible. The same is true of stress. If you learn to recognize the signs of stress and catch yourself early in the process, you may have a chance to avoid some of the harmful consequences such as overeating or being inactive.

Do you have any signs when you are getting stressed?

- **Take a 10-minute "time out."**

Develop a new habit of responding to stress with a "time out"--stop what you are doing and take a few minutes for **yourself**. Do whatever you find helpful that doesn't involve food. Examples:

- a. **Move those muscles.** Research has shown that being active relieves tension, reduces anxiety, and counters depression. So when you notice yourself feeling stressed, make yourself go out for 10 or 15-minute of exercise. The distraction and breathing can do a lot to make you feel better.
- b. **Pamper yourself.** Take a bath. Manicure your nails. Massage your feet. Read a magazine. Read the funnies. **Just take out 10 minutes for YOURSELF.**
- c. **Breathe.** Most of us tend to hold our breath when we are under stress, which creates more tension in the body and mind. So when you catch yourself feeling stressed, try this: Take a full, deep breath. Count to five. Then let go of your breath slowly. Let the muscles in your face, arms, legs, and body go completely loose.

Discuss how study may be a source of stress and ways to manage that stress.

We understand that **the study itself and the lifestyle changes we recommend may cause stress**. Changing your behaviors and helping your family to make related changes can create pressure and tension.

Here are some possible ways that the study may cause stress and some examples of how to manage that stress.

Review the work sheet with the participant. Note that some of the possible sources of stress may not apply to the participant--for example, the participant's family may enjoy low-fat foods. Be careful that the review of the work sheet does not create a negative perspective, and help the participant feel able to cope should such stresses arise.

Assign home activity.

How does the study cause you stress? *[Record on work sheet.]* What are some other major sources of stress in your life? *[Record on work sheet.]* Pick one of the examples you've given, and let's make an action plan for either preventing that stress or coping with it.*[Complete the work sheet.]*

For next week:

- Keep track of your weight, eating and activity.
- Follow your action plan.

Then answer the questions on the work sheet (Did it work? If not, what went wrong?) before we meet next time.

Session 16: Ways to Stay Motivated

Objectives:

In this session, the participant will:

- Receive a certificate of participation.
- Review the participant's progress since Session 1, and if not at goal, develop a plan to improve progress.
- Discuss the importance of motivation and ways to stay motivated.

To Do Before the Session:

Review the participant's progress notes since Session 1. Note any plans that were made to improve weight loss and activity level, which strategies were used, and which were successful or not successful. If the participant is not currently at goal for weight loss and/or activity, refer to the Tool Box for ideas of additional strategies required or optional for particular problems.

If you have copies of some of the participant's past Keeping Track records, review them as well. Note some of the positive changes the participant has made.

Make sure the participant's How Am I Doing? graphs for weight and activity are up to date.

Get materials ready:

- Keeping Track book(s).
- Optional forms for self-monitoring during maintenance, such as the Lifestyle Balance Calendar, if applicable.
- Pages for participant's notebook.
- Lifestyle Balance certificate of participation. There are several versions; choose the version that is appropriate for the participant's level of progress. You may want to print the certificate on special paper and add the participant's name in calligraphy if possible (by computer or by hand). Have the principal investigator at your center sign the certificate before the session.
- Meal plans appropriate for the participant's calorie goal, if applicable.

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity? Were you able to follow your action plan (to prevent or cope with one source of stress)?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant. Graph physical activity.

Give the participant a certificate of participation and introduce the upcoming calendar of sessions.

This is the last of the 16 core sessions of the Lifestyle Balance program.

Congratulations! This certificate is to let you know how very important your participation in the study has been during this time.

Sign the Lifestyle Balance certificate of participation and give it to the participant. Personalize it by mentioning briefly some of the particular contributions and efforts that the participant has made.

It's very important to keep in mind that, even though you have finished the first 16 sessions, the **weight loss and physical activity goals remain in place for the rest of the study**. So at our next visit, we'll talk about how we'll work together in the future to help you...

If the participant hasn't reached the goals, emphasize reaching them and then maintaining them for the rest of the study. If the participant *has* reached both goals, emphasize maintaining them and surpassing them if possible because they are *minimum* goals.

Let's set up an appointment for the next visit

If at all possible, make the appointment for one or two weeks from now. Do **not** go to monthly or bimonthly visits at this point (for a detailed discussion of this issue, see the Manual for Contacts After Core, Session 1). Also, do **not** design a general schedule for the after-core period at this point; wait until the first after-core session when you will discuss the frequency of contact in the context of the goals for the after-core.

Review the participant's progress since Session 1, and if not at goal, develop a plan to improve progress.

Today we're going to talk about ways to stay motivated for the long term, to make healthy eating and being active last for a lifetime. But first, let's review your progress since the beginning of the program.

- **What are some of the major changes you've made to be more active?** Include both what you do to reach your goal (that is, those activities you record) and what you do to be more active in general (the lifestyle activity that you don't record, like taking the stairs instead of an elevator).
- **What changes have you made to eat fewer calories and less fat?**

Briefly record on the work sheet some of the changes made by the participant. Be as specific as possible. Praise and encourage the maintenance of these changes.

Have you reached your weight goal? Your activity goal?

Refer to the How Am I Doing? graphs for weight and activity, and check yes or no on the worksheet.

If the participant is **at goal** for weight loss and activity, praise the progress made.

If the participant is **not at goal** for weight loss or activity, praise whatever progress has been made. Encourage the participant to improve, and develop a plan using the work sheet. **Follow the guidelines in the Tool Box as to which strategies are required to address particular problems identified.** For example, some participants may need to be given meal plans at a lower calorie level.

Discuss the importance of motivation.

In programs like Lifestyle Balance, **motivation is crucial to maintaining healthy eating and physical activity for the long term.** But how to stay motivated is **one of the biggest problems people face.**

One reason it's difficult to stay motivated is the fact that many people do well. This sounds ironic--your progress itself makes it hard to *maintain* that progress. But think back to when you first joined the study. *[Tailor the following examples to the individual participant's experience thus far in the program.]* You may have felt tired when you went up stairs and that motivated you to become more active. Now that you're more active, you can climb stairs without difficulty. So that source of motivation (feeling tired when you climbed stairs) is gone.

It's the same for weight. When you first came into the study, your clothes may have been tight and that motivated you to lose weight. If your clothes are looser on you now, you no longer have tight-fitting clothes as a source of motivation.

Discuss ways to stay motivated.

However, it *is* possible to stay motivated for the long term and, as I said, it is very important to maintaining healthy eating and staying active. Here are some things that other people have found helpful.

1. Stay aware of the benefits you've achieved and hope to achieve.

Again, think back to when you first joined the study. What did you hope to achieve?

Record on the work sheet. Refer the participant back to the work sheet from Session 1A,

Remember Your Purpose, and review. Also **acknowledge any costs** that the participant articulates at this point (or that the participant has discussed with you before). Be aware that, throughout the study, participants will continue to weigh the costs versus the benefits of the program as they perceive them.

Have you reached these goals?

Have you received any benefits that you didn't expect?

What would you like to achieve during the next six months of the study? Let's make a list and then you can review these when you need motivation. *[Record.]*

2. **Recognize your successes.**

What changes in your eating and activity habits do you feel proudest of? What has been easier than you thought it would be? What has been harder than you thought it would be?

When you are feeling low on motivation, think about all of these positive changes and give yourself credit for them. Try not to lose the momentum you have reached so far.

3. **Keep visible signs of your progress so you can see how far you've come.**

- **Post a graph of your weight loss and activity on your refrigerator door.** Not only will it keep you aware of your progress, but loved ones will take note and congratulate you for your movement in the right direction.
- **Mark your activity milestones on a map toward a particular goal.** For example, create a simple map of the number of miles it would take to wheel to a favorite vacation spot or tour a favorite city. Mark milestones along the way (the halfway point, a fun museum to stop at along the way, and so on). You might even want to go on an actual vacation at that place when you reach your goal.
- **Measure yourself at monthly intervals.** Keep track of your progress in terms of specific measurements (for example, waist circumference or the number of belt loops).

4. **Keep track of your weight, eating and activity.**

It's common to "drift" away from new habits. You may gradually make small changes in your eating and activity over a long period of time, and not even be aware that you are slowly going back to your old habits. The best way to prevent this and stay in control is to continue to keep track. Keeping track will help you catch changes before they sneak up on you.

Give the participant optional forms for self-monitoring during maintenance, such as the Lifestyle

Balance Calendar, if applicable.

- **Record your activity daily.**
- **Record what you eat this often:** . *[Fill in the blank. The minimum should be one week per month, but some participants may want to or be willing to continue daily self-monitoring.]*
- **Record your weight on.** *[Fill in the blank, for example, "on Monday mornings."]*

If you gain weight, you will need to keep track more often.

5. **Add variety to your routine.**

We've talked before about how to "jump start" your activity plan. Have you added some variety to keep yourself from being bored with staying active? Have you noticed any difference in how you feel about being active?

The same thing is true with eating. You don't need to use the same low fat salad dressing every night. Experiment with new low fat products. Try new recipes and restaurants. Don't approach healthy eating as a chore. It is an art.

What meals, snacks, or particular foods are you most bored with? Can you think of some ways to vary this part of your eating?

Record the participant's ideas on the work sheet. Examples:

- Use seasonings and flavorings to add flavor to lower-fat dishes. (Review the handout on adding flavor without fat.)
- Try a wide range of fruits, vegetables, and grains.
- Include a variety of colors, textures, and tastes on your plate.
- Make one night a week an "ethnic night," "soup night," or "vegetarian night." Experiment with preparing various recipes for these foods.
- If you eat out often, plan more meals at home.
- If you eat at home often, plan more meals out. (Have you stopped eating out because you're trying to lose weight? Has this left you feeling restricted and deprived? Have you stopped inviting friends over to eat or accepting invitations to eat at their homes? Don't deny yourself the pleasure of social eating. Instead, make a plan for how to handle these times, then try your plan, and see how it works. You may make a few mistakes at first, but it's important to know that you **can** eat out and still eat healthy.)
- Share food preparation and dining with others as a way to relax. Invite people over to prepare dinner together. Cook with your children and spouse.
- Plan potluck dinners around a certain theme and share the best recipes you discover as a group.
- You may want to subscribe to a magazine that includes healthy recipes and food ideas, such as Weight Watchers, Eating Well, or Cooking Light.
- Or take a class to learn how to cook, at least the basics.

If the participant expresses interest in learning more about a specific topic such as ethnic cooking or vegetarian eating, address it briefly here and plan to provide more detail at a future meeting or group session.

6. **Set new goals for yourself, and develop ways to reward yourself when you meet each goal.**

The **goal** should be **specific and short-term** (“I will not use butter or margarine on my vegetables this week”). It should also be something that’s not too easy or too hard(something that will present “**just enough**” of a **challenge** for you that you will be able to do it and will also feel that you’ve accomplished something).

The **reward** should be **something that you will do or buy if and only if you reach your goal**. The reward doesn’t need to be fancy or cost a lot of money. It can be something that you normally enjoy doing (like reading the paper or taking a hot bath) with the difference being that you will do it *only if* you reach your goal. For example, “ After I finish exercising, I’ll call my friend and chat.” Then, if you need a boost to keep you going during your exercise, you can think about what you’ll talk about on the phone with your friend.

What are some non-food ways you can reward yourself for reaching a goal?

Record ideas on the worksheet, such as:

- Buy myself fresh flowers,
- Treat myself to a manicure,
- Go to a movie,
- Set some money aside for something you want to buy or do,
- Take a bubble bath,
- Buy a favorite magazine, or
- Take some time for myself. (Specify.)

7. **Create some friendly competition.**

Get a friend or relative to enter into a friendly competition with you. This should be the **kind of competition in which you both win**. For example:

- If you and your friend are both active every day for a month, at the end of the month what will you do?
- If you are active every day for a month and your daughter does her homework every day, at the end of the month what will you treat yourselves to?
- See how many days in a row you can be active for at least 30 minutes. Try to beat yourself. For example, if last month you were active for seven days in a row, see if you can do better this month.

8. **Use me and others to help you stay motivated.**

If you notice that your motivation is dropping, call me. Or call someone else on the Lifestyle Balance staff. Or call a friend or another participant. Everyone has trouble staying motivated sometimes, so we all understand. And we can help each other through the tough times.

9. **Introduce Viterion 100 system.**

We will be contacting you going forward on a biweekly basis to monitor your progress. We will ask you a few questions about your level of exercise and your caloric intake. If we find that you are maintaining your goals, then we will not contact you more than the pre-planned amount. If the responses indicate that you are having a “slip,” then the lifestyle coach will give you a call to see what’s going on and try to help you get back on track.

Train the participant in the use of the Viterion machine and see if he has any questions.

Assign home activity.

Pick one way to stay motivated that you think would be most helpful to you right now. Choose something that is very likely to work and that you can do. Be realistic. Be specific. (*Record on work sheet.*)Let’s **make an action plan** related to that. (*Complete the work sheet.*)For next week, keep track of your eating and activity. Follow your action plan. And answer the questions on the work sheet before you come in for your next session.

WEIGHT MIRROR

General Principles:

- As a component of the Behavioral Intervention, the Internet based freeware, Weight Mirror, will be used to create a 'virtual image' of the participant that is 7% lighter than their measured weight at the onset of the study.
- Visualization of weight loss, in this manner, will be used as a motivational tool.
- A photograph of the participant will be taken at the onset of the study, and uploaded to the Weight Mirror program for virtual image creation. The area of interest on the website will include eyes to knees inclusive of right/left body dimension.
- Original photograph will be used as a reference along with the virtual image, and included in the Lifestyle Manual to be given to each participant
- Photographs will be updated at 6, 12, and 18 months
- <http://makeovr.com/weightmirror/>



Figure 4. A woman with paraplegia before (left) and after (right) a 7% 'virtual' weight loss.

EXTENTION PHASE - MONTHLY INTERVENTION.	
Topic	
Data Collection	<input type="checkbox"/>
Review of self-monitoring records	<input type="checkbox"/>
Review of homework	<input type="checkbox"/>
Introduction of new topics*	<input type="checkbox"/>
Completion of action plan	<input type="checkbox"/>
Scheduling of next meeting	<input type="checkbox"/>

*only on bi-monthly *face-to-face* meeting with life-style coach.

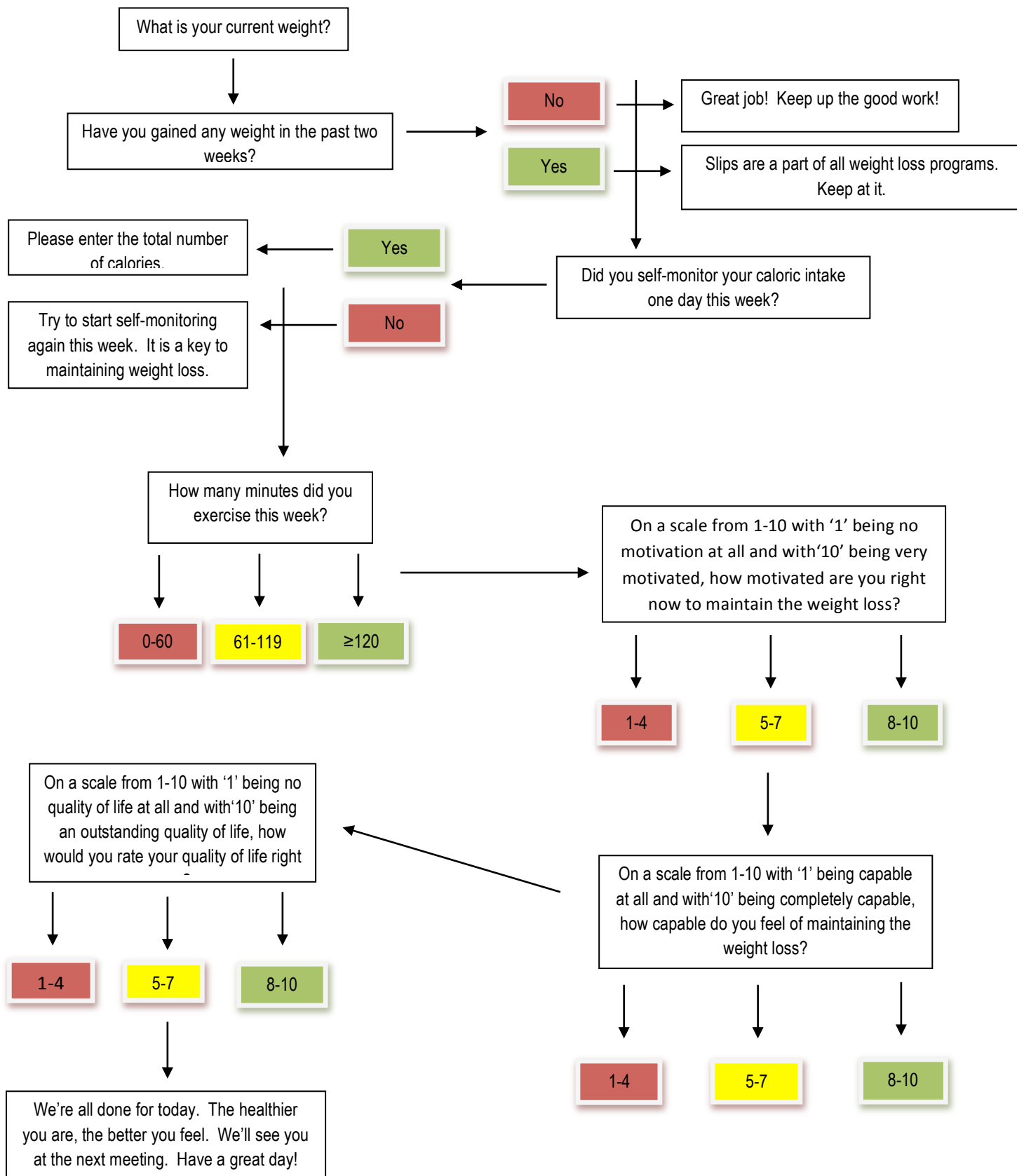
TeleHealth Network:

- Participants will be provided with a **Viterion 100 TeleHealth device** that connects directly to the home phone line.
- **NO** computer, wireless network, modem, or Ethernet link is required.
- Lifestyle coaches can automatically be connected with participants through the TeleHealth system.
- TeleHealth allows patients to receive education and self-management tips **DAILY**.
- Information received by the home TeleHealth device is viewed daily via a secure internet site by an RN/ARNNP-assigned care coordinator.

“Toolbox” Options:

- As employed by the DPP, toolbox options will be utilized by life-style coach’s motivation and adherence to the core and extension lifestyle intervention.
- These options will include awards for compliance, effort, and success.
- Problem solving strategies will be included to mitigate problem behaviors such as poor attendance, insufficient self-monitoring, unmet weight loss goals/maintenance, and unmet physical activity goals.

PROTOCOL FOR PARTICIPANTS USING THE VITERION 100 TELEHEALTH DEVICE

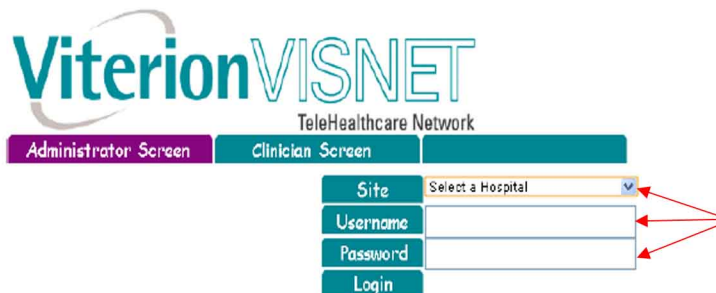


Enrolling a patient into the Viterion system:

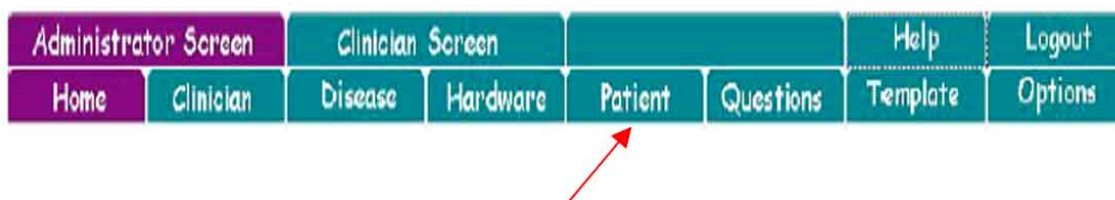
- Using your web browser navigate to <https://vaww.viterion.cc.med.va.gov/visnet>
- The Viterion homepage will appear:



- Click on the ADMINISTRATOR tab
- The LOGIN screen will appear:



- Trained personnel can access the system by entering the appropriate SITE, USERNAME, and PASSWORD
- Click on the LOGIN tab to load the following screen:



- Select the PATIENT tab

- Selecting DEMOGRAPHICS from the dropdown menu will allow you to add patient data:

Patient name

To add a patient, select "-Add New Patient-" from the patient dropdown list. To modify a patient, select the patient name from the dropdown list.

Personal Information			
*First name	<input type="text"/>	Middle name	<input type="text"/>
*Gender	<input type="text" value="-Select Gender-"/>	*Date of birth	<input type="text"/> Calendar MM/DD/YYYY
*Address	<input type="text"/>		*City
*State	<input type="text" value="-Select State-"/>	*Zip code	<input type="text"/>
*Phone	<input type="text"/>	Secondary phone	<input type="text"/>
Email	<input type="text"/>		*Language <input type="text" value="English"/>
Comments	<input type="text"/>		
*Program of care	<input type="text" value="-Select Program-"/>		
Emergency contact information			
Primary name	<input type="text"/>	Phone	<input type="text"/>
Secondary name	<input type="text"/>	Phone	<input type="text"/>
Pharmacy name	<input type="text"/>	Pharmacy phone	<input type="text"/>
Doctor name	<input type="text"/>	Doctor phone	<input type="text"/>

- Select ADD NEW PATIENT from the drop down menu
- Enter personal information and emergency contact information
- Click SAVE
- Subsequent patient information pages will load:

Diseases			
<input type="checkbox"/> Spinal Cord Injury	<input type="checkbox"/> CHF	<input type="checkbox"/> Chronic Renal Failure	
Clinician List			
	Unassigned		Assigned
	Jones, Betty Brown, Kate	<input type="button" value="→"/>	
		<input type="button" value="←"/>	
<input type="button" value="Save"/> <input type="button" value="Save and assign mentor"/> <input type="button" value="Delete"/>			

- Check/Select SPINAL CORD INJURY from the DISEASE table
- Highlight the name(s) of the appropriate clinician(s) that will be assigned to the patient and use the arrow keys to move them to the ASSIGNED column
- Click SAVE
- A series of similar patient information tables, and specific limits for peripheral anthropometric and biological data collection can be entered and saved:

The screenshot shows a web-based patient information system. At the top, there is a 'Patient name' dropdown menu with '- Select Patient -' selected. Below this is the 'Assigned Monitors' section, which includes a 'Viterion 100 serial number: 999999' and buttons for 'Modify' and 'Unassign Monitor'. The 'Add/Update Monitor' section has a dropdown menu with '- Add/Update Monitor -' selected. The 'Vital Signs' section contains a list of vital signs with checkboxes and dropdown menus for device selection: Blood Glucose (Bayer/Ascensia Elite XL), Blood Oxygen (Nonin/i-pod), Blood Pressure (A&D medical/JA-767PC), Fluid Level (Manual Input Type), Pain (Pain Rating (0-10 Scale)), Peak Flow (Manual Input Type), PT/INR (Manual Input Type (INR/PT)), Temperature (Manual Input Type), Weight (A&D medical/UC-321), Questions (CHF), and Question Calendar (No Question Calendar). The 'Monitors' section has a 'Select Monitor' dropdown with 'No Monitor' selected. Below this is the 'Monitor login information' section, which includes fields for 'Screen name', 'Passcode', and 'Sound', along with 'Search', 'Select', and 'Play' buttons. At the bottom of the 'Monitors' section are 'Save' and 'Save and Set Limits' buttons. The 'Blood Glucose' section features a table with risk levels and numerical ranges, and a 'Save All' button at the bottom. Red arrows point to the 'Patient name' dropdown, the 'Add/Update Monitor' dropdown, the 'Search' button, the 'Select' button, and the 'Save All' button.

Assigned Monitors
 Viterion 100 serial number: 999999 [Modify](#) [Unassign Monitor](#)

Add/Update Monitor - Add/Update Monitor -

Vital Signs

<input type="checkbox"/> Blood Glucose	Bayer/Ascensia Elite XL
<input type="checkbox"/> Blood Oxygen	Nonin/i-pod
<input type="checkbox"/> Blood Pressure	A&D medical/JA-767PC
<input type="checkbox"/> Fluid Level	Manual Input Type
<input type="checkbox"/> Pain	Pain Rating (0-10 Scale)
<input type="checkbox"/> Peak Flow	Manual Input Type
<input type="checkbox"/> PT/INR	Manual Input Type (INR/PT)
<input type="checkbox"/> Temperature	Manual Input Type
<input type="checkbox"/> Weight	A&D medical/UC-321
Questions	CHF
Question Calendar	No Question Calendar

Monitors

Select Monitor: No Monitor

Monitor login information

Screen name	Passcode	Sound	Select	Play
			- Select Sound -	

[Save](#) [Save and Set Limits](#)

Blood Glucose

High risk	Moderate risk	Normal range	Moderate risk	High risk
Below moderate	10 mg/dL below min	Min 80 max 120 mg/dL	20 mg/dL above max	Above moderate
Below 70	70 - 79.9	80 - 120	120.1 - 140	Above 140

[Save All](#)

- Verify the patient
- Select appropriate monitor type
- Check appropriate boxes if any vital signs will be monitored
- Click SAVE
- Enter any limits
- Click SAVE ALL

PERSONNEL SET UP AS CLINICIANS CAN ACCESS ADDITIONAL DATA:



- Click on the CLINICIAN tab
- The LOGIN screen will appear:

The image shows the ViterionVISNET TeleHealthcare Network login screen. At the top is the logo. Below it are two tabs: 'Administrator Screen' and 'Clinician Screen'. The 'Clinician Screen' is selected. Below the tabs are four fields: 'Site' (a dropdown menu with 'Select a Hospital' and a blue arrow icon), 'Username' (a text input field), 'Password' (a text input field), and 'Login' (a button). Red arrows point to the 'Site', 'Username', and 'Password' fields.

- Enter the appropriate SITE, USERNAME, and PASSWORD
- Click on the LOGIN screen
- This will load the CLINICAL page:

Patient name **Run Report**

Start date **Calendar**
End date **Calendar**

Patient Information

Name: Phone:
 SSN: ID:

Blood Pressure **Graph**

Measurement	Transmit Date	Measurement Date	Systolic	Diastolic	Pulse
BP	06/25/2007 1:58:19 PM	06/25/2007 10:54:30 AM	138	83	108
BP	06/27/2007 3:55:44 PM	06/26/2007 10:41:47 AM	140	75	112
BP	06/27/2007 4:01:37 PM	06/27/2007 12:58:06 PM	98	66	108
BP	06/29/2007 2:37:51 PM	06/29/2007 11:35:38 AM	137	75	103
BP	06/30/2007 2:22:39 PM	06/30/2007 11:20:28 AM	94	55	103

- Select the appropriate patient's name from the dropdown menu
- Select the start date and the end date of the data you wish to see by clicking on the calendar buttons and choosing the date
- Click the RUN REPORT button; It will take a few seconds to generate the report

CIRCUIT RESISTANCE TRAINING (CRT).

General principles:

- **CRT** is a mode of training that employs lockstep resistance maneuvers interposed with short periods of un-resisted, high velocity arm work.
- Study participants will undergo **CRT three times per week** on non-consecutive days for **24 weeks**.
- Resistive loads for training during weeks 1 and 2 of each month will be **50%** of the 1-repetition maximal (1RM) values calculated during initial isoinertial strength testing.
- Resistive loads will be increased to 55% and 60% of the 1RM during training weeks three and four for each month, respectively.
- 1RM strength will be assessed as follows:
 - ☐ Subjects will be instructed to perform 8 repetitions of each maneuver with each repetition lasting six seconds (3 seconds concentric, 3 seconds eccentric).
 - ☐ If 8 repetitions are completed in a controlled fashion, weight will be increased and the exercise repeated – incremental increases will be 5 kg (paraplegia) and 2.5 kg (tetraplegia) until 8 repetitions **cannot** be completed.
 - ☐ 1RM will be calculated using the Mayhew regression equation:

$$1RM = Wt / (0.533 + 0.419e^{-0.055 \cdot REPS})$$

where **1RM** is the calculated one repetition maximum strength, **Wt** is the resistance used in the last set where more than three repetitions but less than eight repetitions were completed, and **reps** equals the number of repetitions completed in the last set of testing.

- 1RM will be assessed in the following time schedule:

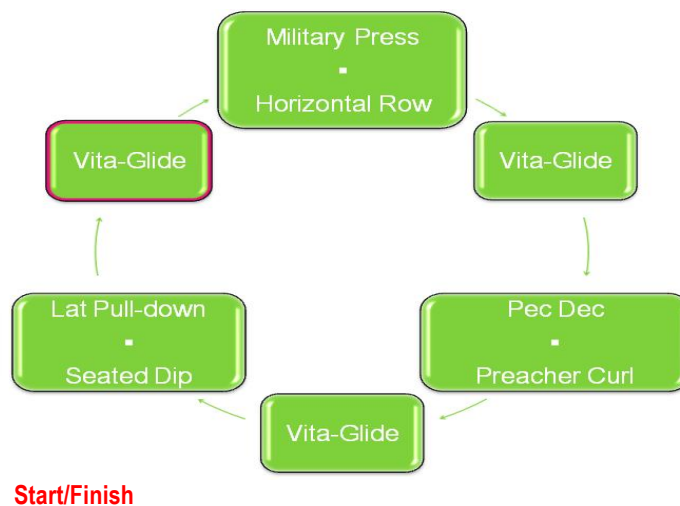
Exercise Maneuver	Upper extremity dynamic strength (1RM)									
	-3	0	1	2	3	4	5	6	12	18
Military press	▪	▪			▪			▪		
Horizontal rows	▪	▪			▪			▪		
Pec dec	▪	▪			▪			▪		
Preacher curls	▪	▪			▪			▪		
Latissimus pull-downs	▪	▪			▪			▪		
Seated dips ("Rickshaw")	▪	▪			▪			▪		

DESCRIPTION OF EXERCISE MANEUVERS UTILIZED IN CRT.

Exercise Maneuver	Description
Military Press	Shoulder abduction with scapular elevation and upward rotation starting from the fully adducted and depressed position.
Horizontal rows	Shoulder horizontal abduction with scapular adduction starting from a position of maximum forward reach.
Pec dec	Shoulder horizontal adduction while in external rotation to the midline, from the maximum tolerated horizontal abduction in external rotation.
Preacher curls	Elbow flexion supported on an inclined pad from the fully extended position.
Latissimus pull-downs	Shoulder adduction with scapular downward rotation and depression starting from the maximal upward reach position.
Seated dips ("Rickshaw")	Shoulder flexion, scapular depression, and elbow extension while maintaining arms as near the body as possible, from the fullest allowed point of shoulder joint extension, scapular elevation, and elbow flexion.

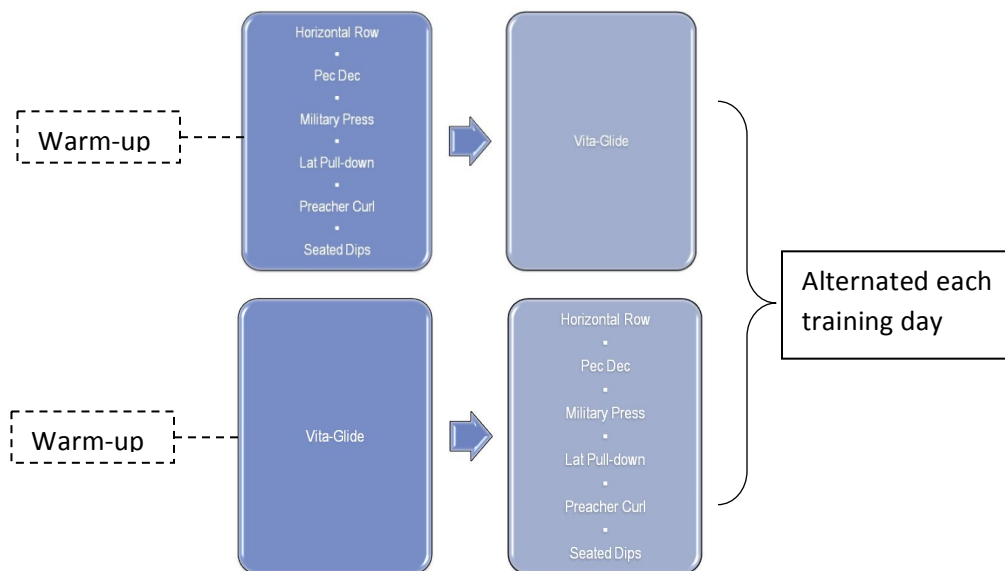
CRT training session design:

- Each training session will be preceded by a 2-minute warm-up on a Vita-glide® arm ergometer.
- Resistance exercises will be performed in pairs (2 maneuvers in succession) each incorporating 10 repetitions of each maneuver lasting six seconds (3 seconds concentric, 3 seconds eccentric).
- Two minutes of endurance exercise is then interposed using a Vita-glide® arm ergometer at a cadence of 50 rpm without applied resistance
- Two more resistance maneuvers are performed.
- These activities are alternated until the participant has rotated through each resistance station **three times**.



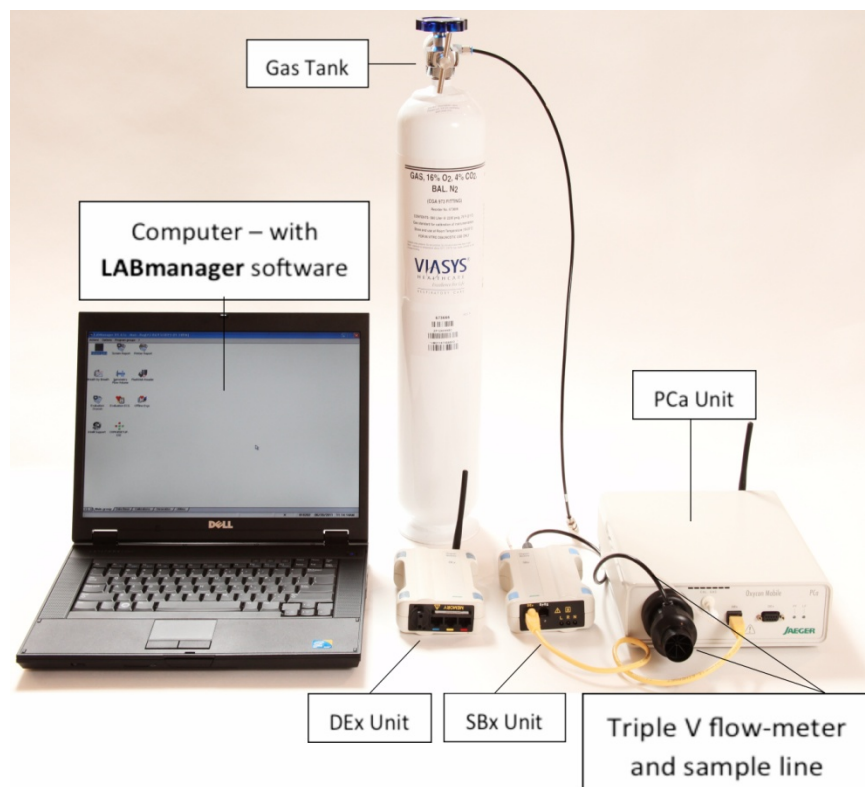
Modifications to CRT for participants with tetraplegia:

- Adaptations to work-out for persons with tetraplegia as high as the C5 level.
- Resistance maneuver order is altered to reduce time needed for changing the resistance stations.
- Resistance and endurance exercises are performed in contiguous time blocks – order of exercise (i.e. resistance and endurance) are alternated on each training day.
- Each training session will be preceded by a 10-minute warm-up on a Vita-glide® arm ergometer.
- Each resistance station will be performed **twice only**.



OXYCON MOBILE – INSTRUCTIONS/PROTOCOL.

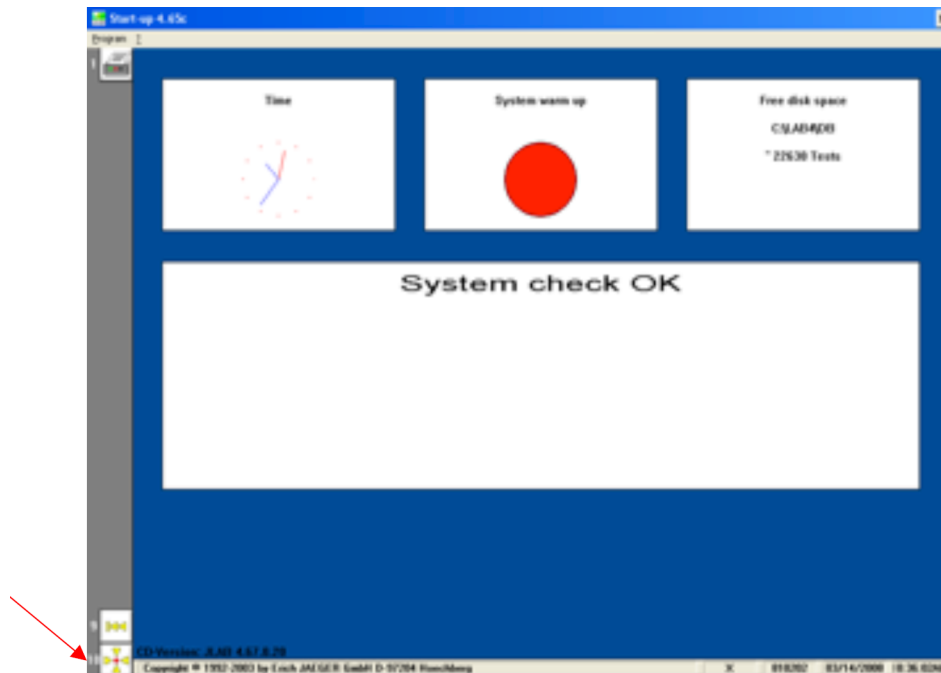
Equipment Set-up:



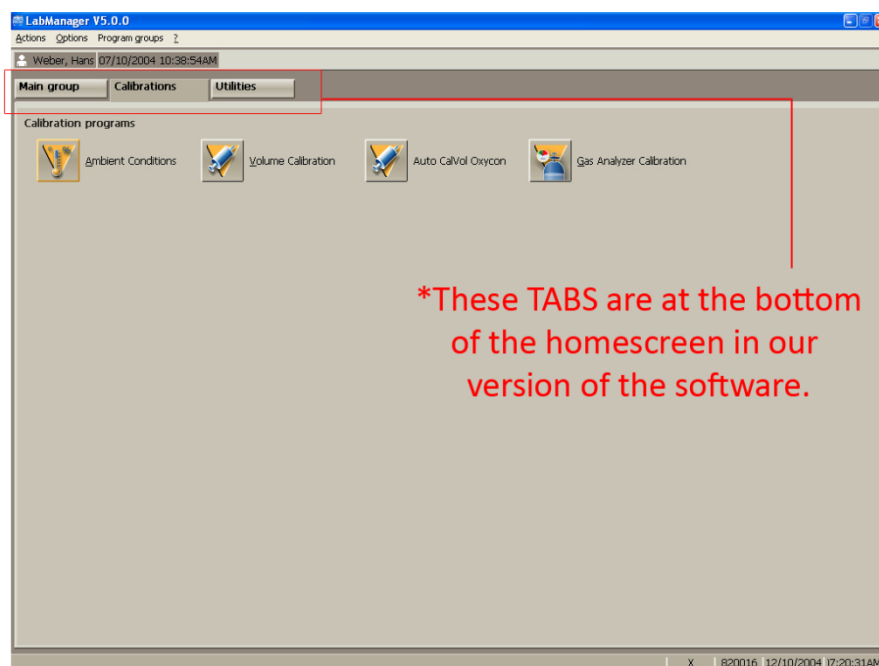
- Connect computer to power source using A/C adaptor
- Connect PCa unit to power source using A/C adaptor – Green light should turn on automatically (FF-full functionality)
- Turn computer on – LOG IN
- Connect PCa to computer via gray USB cable
- Connect gas tank to the back of the PCa unit
- Connect the Triple V flow-meter, sample line and cable (yellow) into the appropriate ports on the back of the SBx unit
- Connect the Triple V flow-meter into the *Cal flow* slot, the sample line into the *Cal gas* slot, and cable into the SBx ports on the PCa unit – Should hear a buzzing from the SBx mobile unit
- Ensure battery for the DEx mobile unit is charged – load into DEx mobile unit

Calibration:

- Load LABmanager program
 - When self-test is completed, screen will read SYSTEM CHECK OK



- Select 10 (SAVE) at the bottom left – This will open the LABmanager testing program
- Select the CALIBRATION tab located at the bottom of the HOME screen

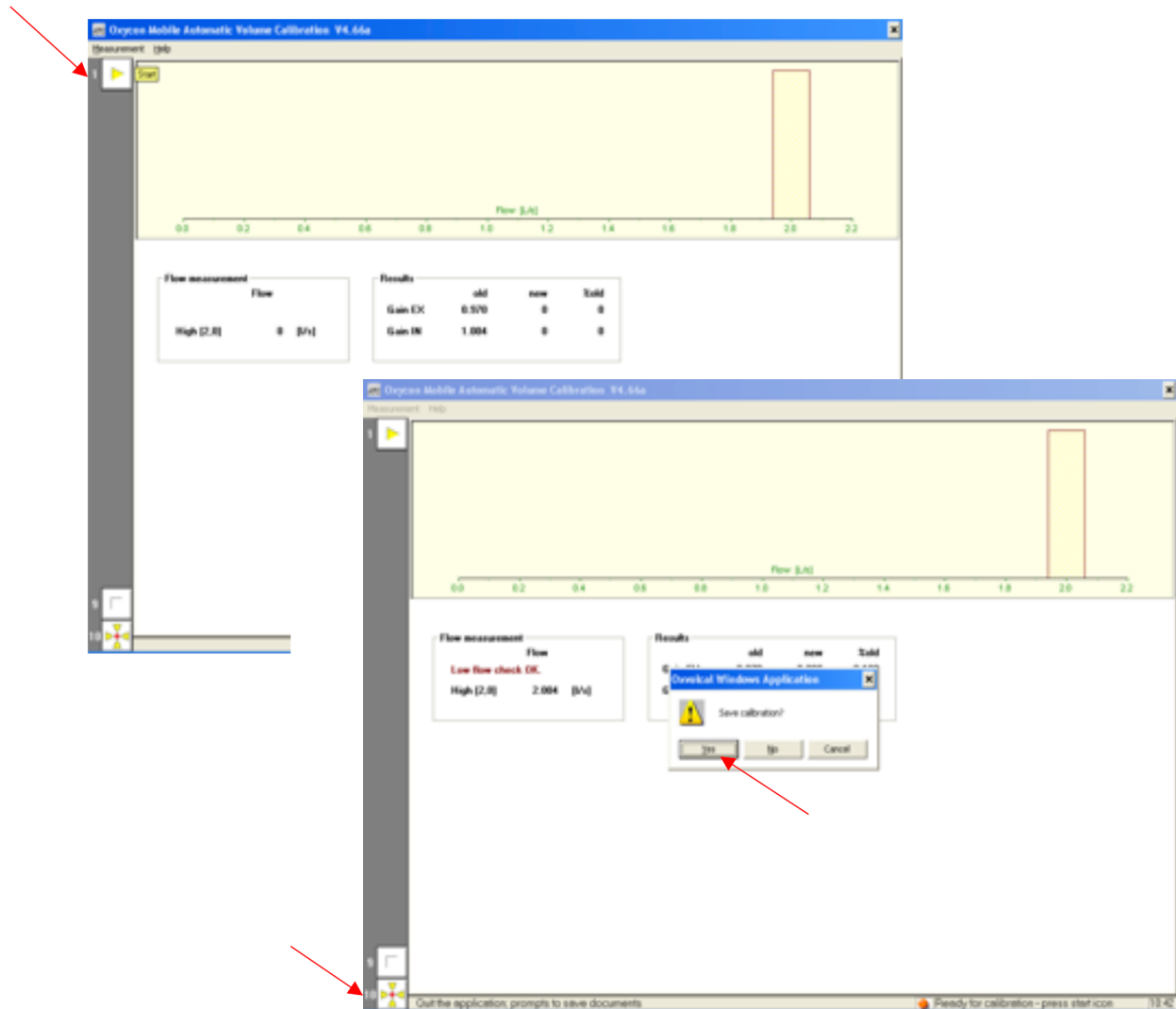


*These TABS are at the bottom of the homescreen in our version of the software.

HOME SCREEN

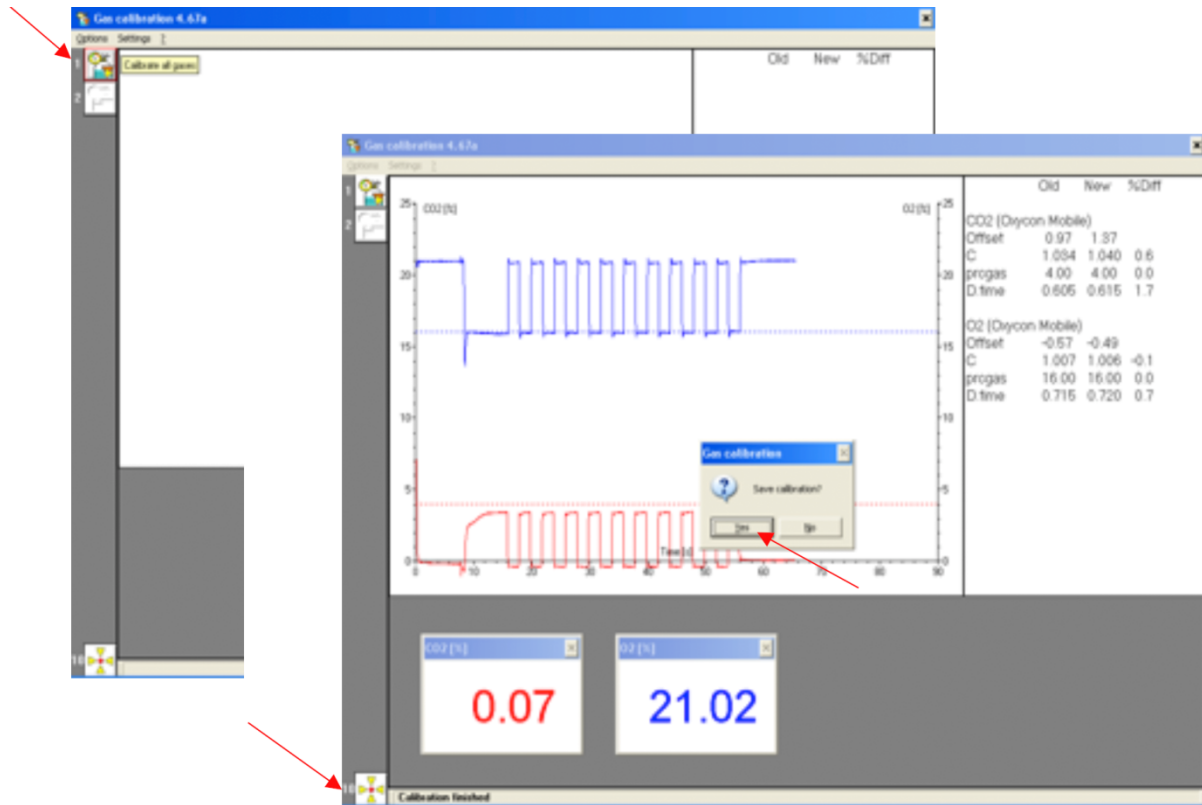
□ Select AUTO CALVOL OXYCON

- Select 1 (START) at the top left – Auto flow calibration will commence (High flow init. – High flow measure – low flow init. – low flow measure – low flow check OK)
- Select 10 (SAVE) at the bottom left, when the calibration is complete – click YES to save calibration



□ Select GAS ANALYZER CALIBRATION

- Select 1 (START) at the top left – Auto gas calibration will commence
- Select 10 (SAVE) at the bottom left, when the calibration is complete – click YES to save calibration



Patient Data Entry:

- Select the MAIN GROUP tab located at the bottom of the HOME screen
 - Select PATIENT DATA
 - Enter name, ID, DOB, sex, height, weight, race
 - Select 10 (SAVE) at the bottom left, and EXIT

The screenshot shows a software window titled 'Patient V5.04c'. Inside, there's a form for entering patient data. The form has a left sidebar with icons and a main area with various input fields. A red arrow points to a button labeled '10' at the bottom left of the form, which is part of a search bar that says 'Name of patient. Search is also possible with...'.

Subject Preparation:

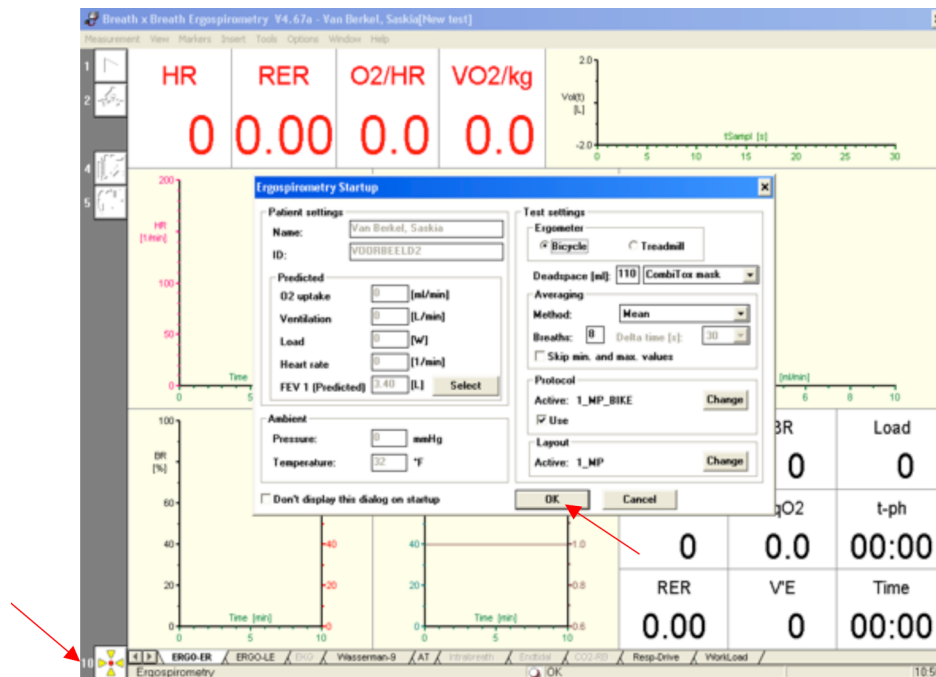
- Securely fasten POLAR BELT heart monitor to subject
 - Apply PURELL to belt to ensure proper contact with the skin
- Attach DEx and SBx units to each other by connecting the cable (already attached to SBx unit) in to the DEx unit – Should hear a buzzing from the SBx mobile unit
- Remove the Triple V flow-meter and sample line from PCa, and insert sample line in to the Triple V
- Secure harness system to subject, and securely attach the DEx and SBx units into the pouches in the front of the harness
- Place the Triple V flow-meter/sample line on the subjects lap for the time being
- Attach face mask using appropriate head strap
 - Cover the mouth opening with the open palm of your hand and instruct the subject to breathe normally – if no air escapes, the mask is appropriately secure



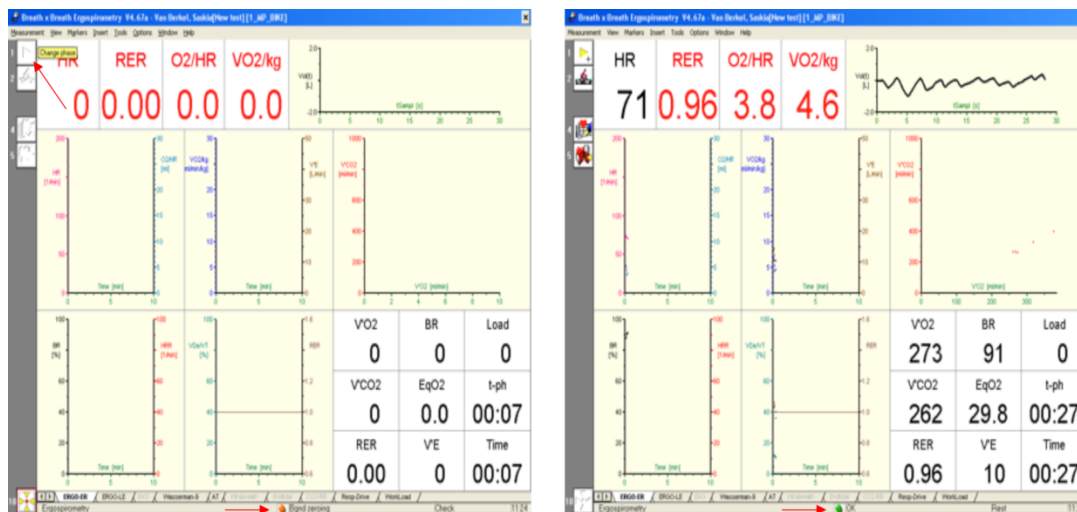
Testing:

**DO NOT attach Triple V and sample line to the subject at this time*

- Select the MAIN GROUP tab located at the bottom of the HOME screen
 - Select BREATH BY BREATH
 - Select appropriate test setting (bicycle = wheelchair)
 - Select appropriate protocol (ie Phase selection is manual)



- Select 1 (START)
 - **CHECK** phase begins
 - No sample collection initially – status line: ●bgnd zeroing
 - Automatic - Sample collection begin – status line: ● OK



**Attach Triple V and sample line to the subject at this time*

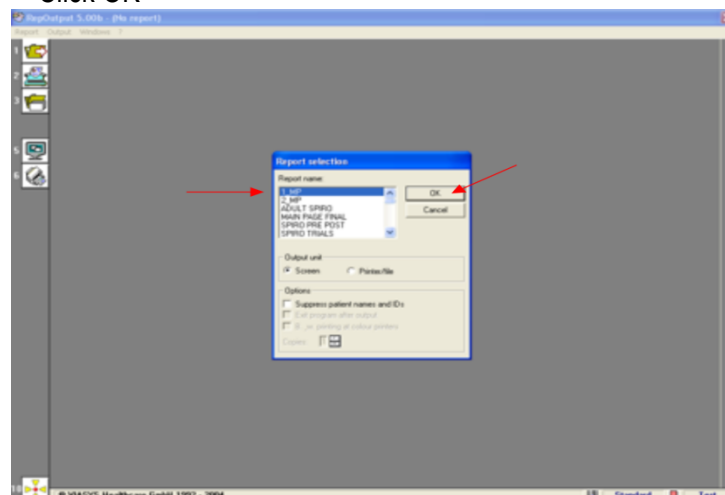
- ☐ Select 1 (START)
 - **REST** phase begins
 - Data will be collected in this phase until the start of the next phase is manually selected
- ☐ Select 1 (START)
 - **WARM-UP** (REFERENCE) phase begins
 - Data will be collected in this phase until the start of the next phase is manually selected
- ☐ Select 1 (START)
 - **TEST** phase begins
 - Data will be collected in this phase until the start of the next phase is manually selected
- ☐ Select 1 (START)
 - **RECOVERY** phase begins
 - Data will be collected in this phase until the protocol is stopped
- ☐ Select 1 (**STOP**) – Ends the protocol and test data collection (Status line READY)

Subject:

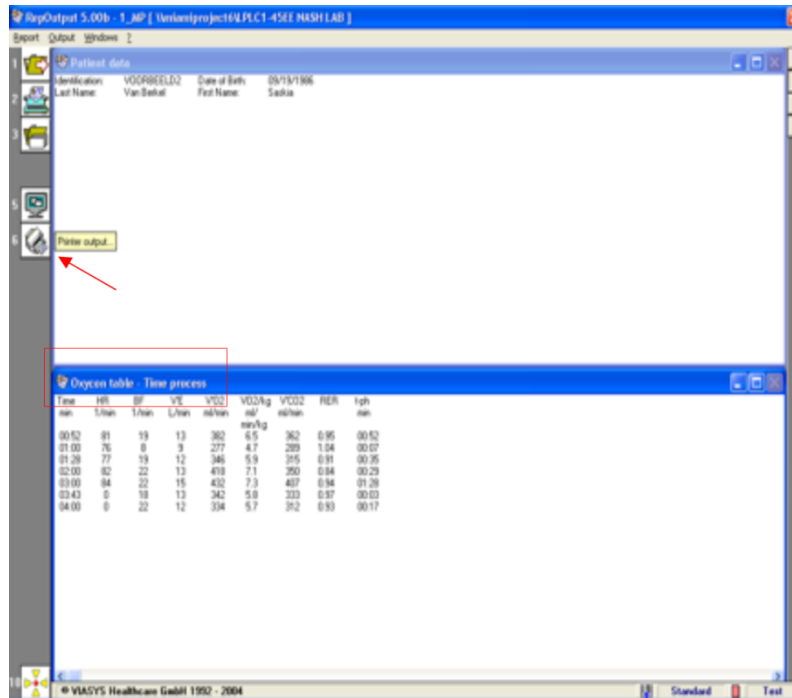
- Remove triple V flow meter from the face mask
- Remove facemask
- Remove DEx and SBx units from the belt/harness system and the belt/harness system off
- Turn the DEx and SBx units off
- Take the battery out of the DEx unit and place it in the battery charger
- Remove the polar belt
- Put water and disinfectant in a bowl and clean face mask, head strap, polar belt and polar belt strap

Retrieving subject test data:

- Select the MAIN GROUP tab located at the bottom of the HOME screen
 - ☐ Select SCREEN REPORT
 - Highlight the report selection desired (i.e. 1_MP)
 - Click OK

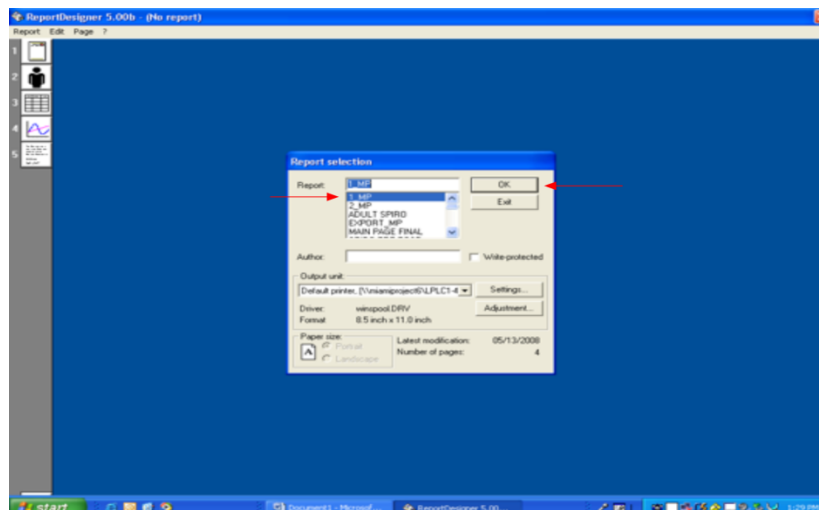


- ☐ Select OxyCon table – Time process (the bottom half of the screen)
- ☐ Highlight the Oxycon Table – Time Process tab/window
- ☐ Click '6' – Print Output on the left-hand side of the screen

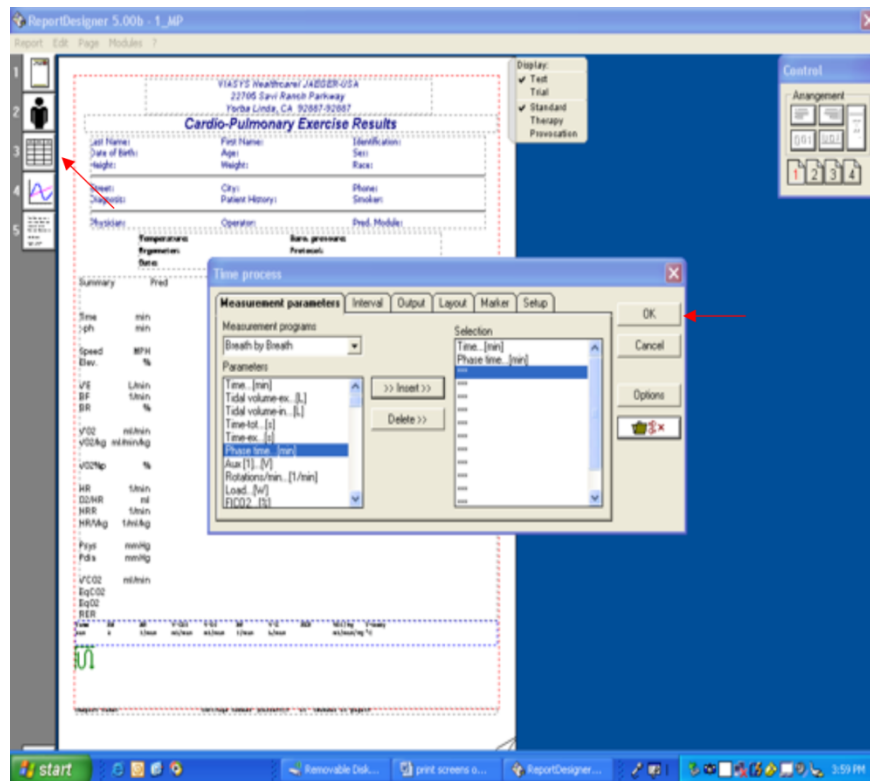


Designing Reports:

- Select the GENERATION tab located at the bottom of the HOME screen
 - ☐ Enter password
 - ☐ Select REPORT DESIGNER
 - Highlight the Report Selection desired (i.e. 1_MP)
 - Click OK

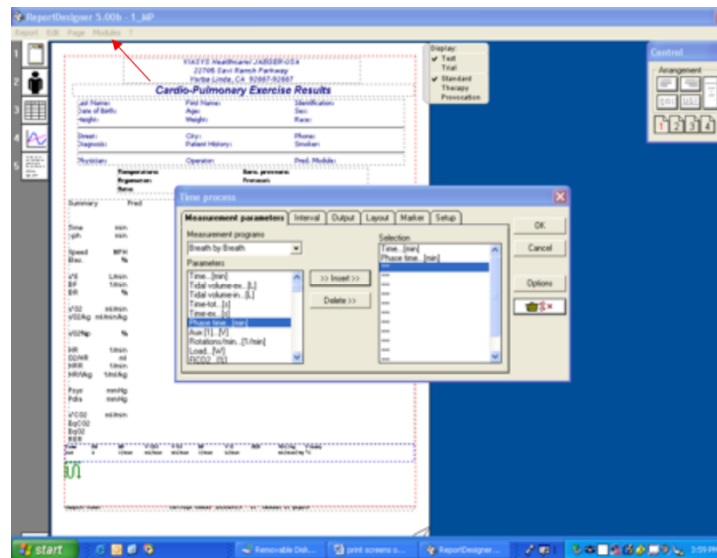


- Select 3 (REPORT DESIGN)
 - Select OXYCON TABLE
 - Select TIME PROCESS
 - Insert the desired variables
 - Click OK
 - Select "X" to exit program
 - Select YES to "Save Report?"

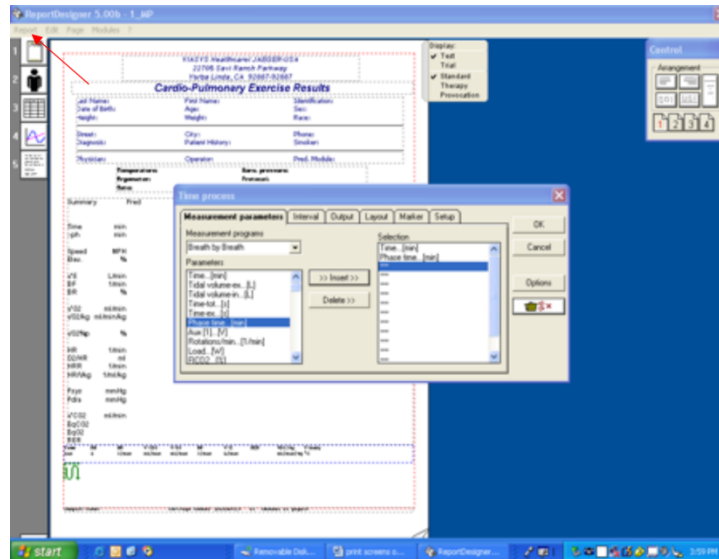


Exporting data from report designer to excel:

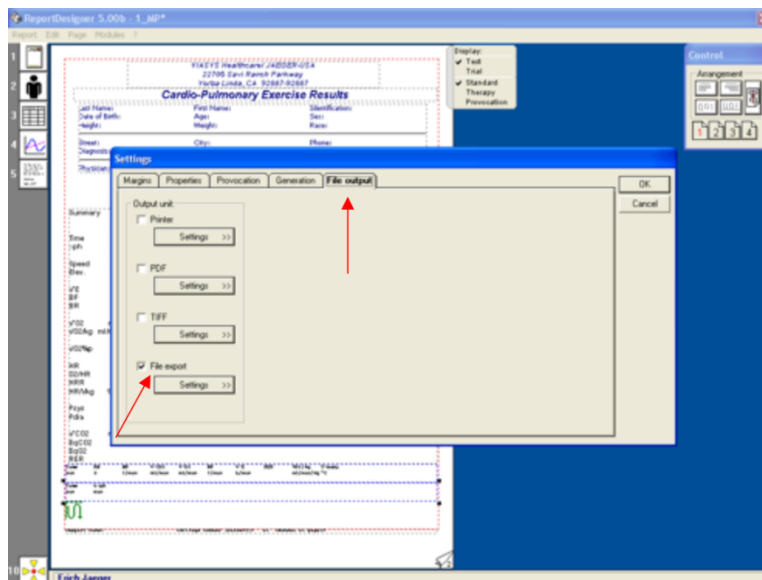
- Select the GENERATION tab located at the bottom of the HOME screen
 - ☐ Enter password
 - ☐ Select REPORT DESIGNER
 - Highlight the Report Selection desired (i.e. 1_MP)
 - Click OK (*As described)
 - ☐ Select the “MODULES” tab in the upper left-hand side



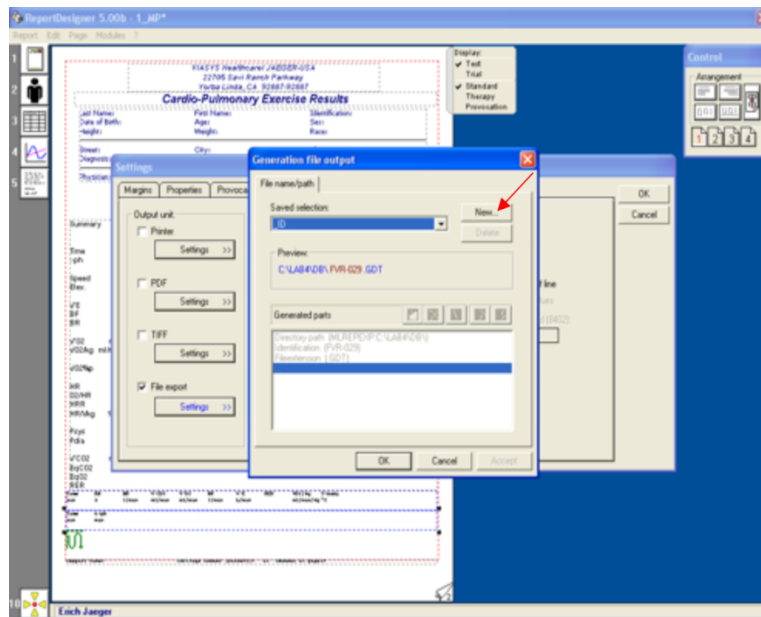
- ☐ Select TABLE→OXYCON TABLE→TIME PROCESS
- ☐ Insert desired variables
- ☐ Click OK
- ☐ You will be returned to the main menu of Report Designer
- ☐ Select the “REPORT” tab in the upper left-hand side
- ☐ Select “SETTING”



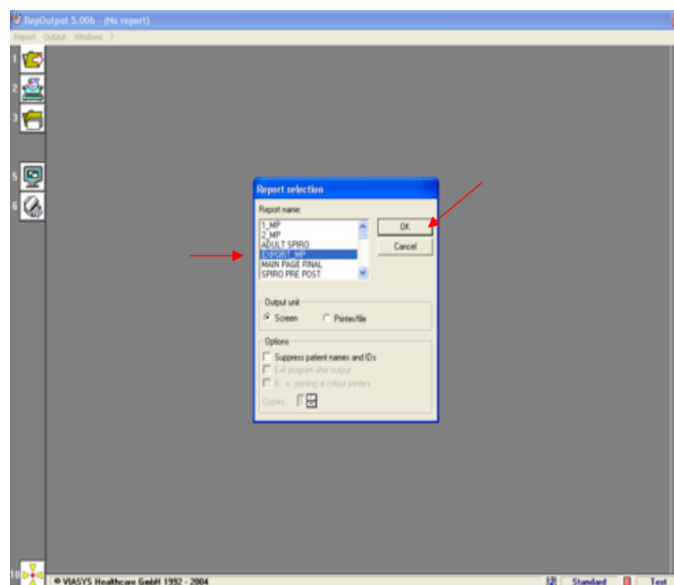
- ☐ A new window will appear
- ☐ Select "FILE OUTPUT" → Check "FILE EXPORT"
- ☐ Select the "SETTINGS" button underneath "FILE EXPORT"



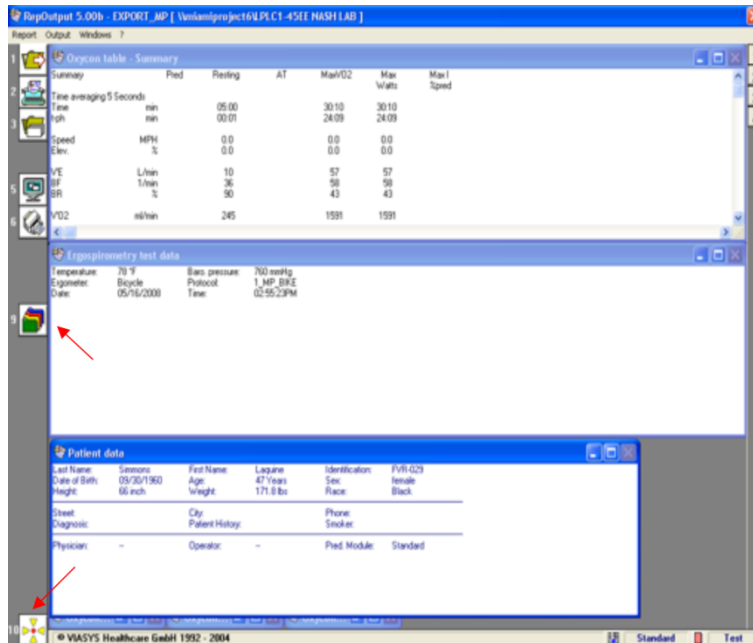
- Select as follows:
 - No formatting
 - Select CR/LF
 - Select ANSI (Windows)
 - Check Mark: "Unlimited Length of Line"
 - Select the "FILE NAME/OPTIONS" button
 - Select "NEW" and create a new entry
 - Click OK



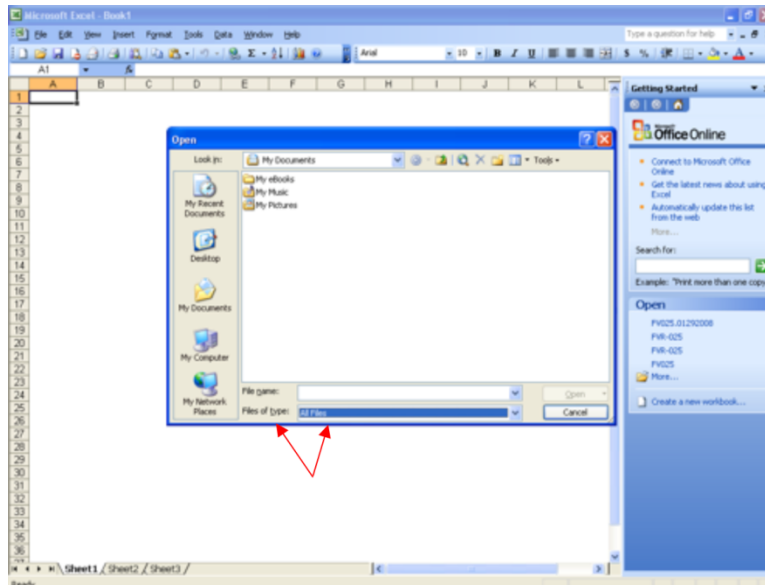
- ☐ You will be returned to the “FILE OUTPUT” window
 - ☐ Click OK to save changes
 - ☐ Select the “REPORT” tab on the upper left-hand side
 - ☐ Select “SAVE AS” and save report
 - ☐ Select 10 (SAVE) on the lower left-hand side to save and EXIT
- Select the MAIN GROUP tab at the bottom of the HOME screen
 - ☐ Select REPORT SELECTION
 - ☐ Select the appropriate report
 - ☐ Click OK



- Select 9 (FILE OUTPUT)
- Select 10 (SAVE) to save and EXIT

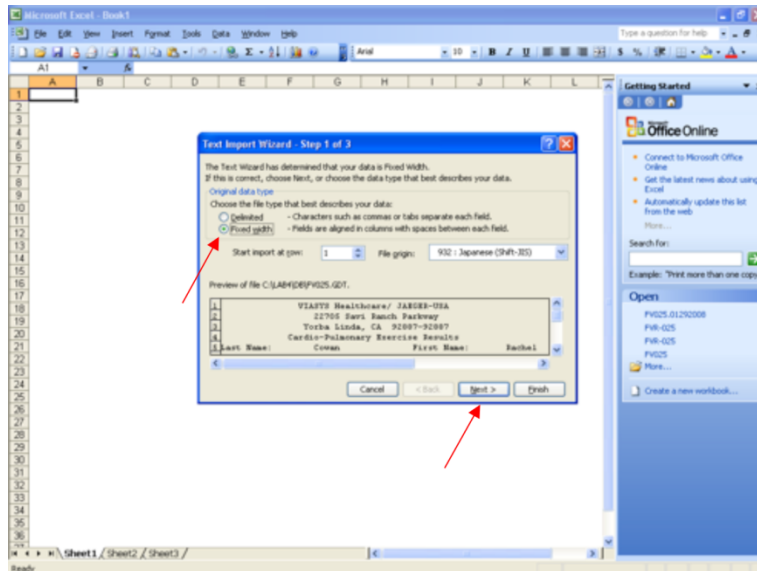


- IMPORT DATA:
 - Open MICROSOFT EXCEL
 - Select FILE→OPEN
 - Select "FILE TYPES"→ "ALL FILES"

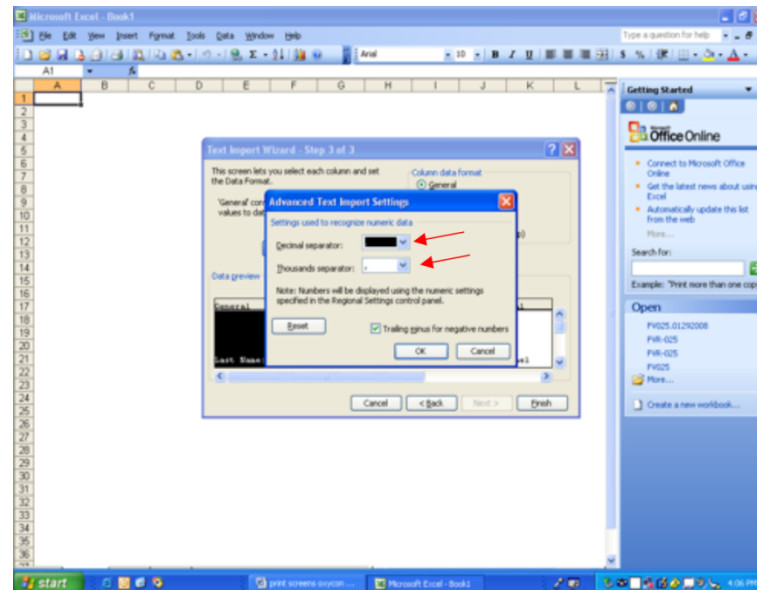


- Navigate to local disk (:C)→LAB4→DB→Select desired FILE
- Click OPEN
- TEXT IMPORT WIZARD window appears

- Select “FIXED WIDTH”
- Select NEXT→NEXT



- Select ADVANCED
- Use the following settings:
 - Decimal separator “.”
 - Thousand Separator “,”



- Click OK
- Select FINISH
- Subject data appears in EXCEL→FORMAT→SAVE as xlsx

Using the Flash Card:

If the **Oxycon Mobile** is active, the measured data are telemetrically transmitted to the PCa and thus to the PC. Should the transmission be disturbed, the measuring data are not received correctly. As, however, the measuring data are not only sent but simultaneously saved on a Flash Card, it is possible to read the Flash Card data. In order to save the measuring data, insert the Flash Card in the DEx unit. Use the Flash Card Reader which is included in the delivery of the **Oxycon Mobile** to read out the saved data. The Flash Card Reader is connected to your PC via the USB interface.



1. Select patient

Prior to reading the Flash Card, a patient must be selected to whom the data are to be assigned. More detailed information can be found under "Patient Data" in this manual.

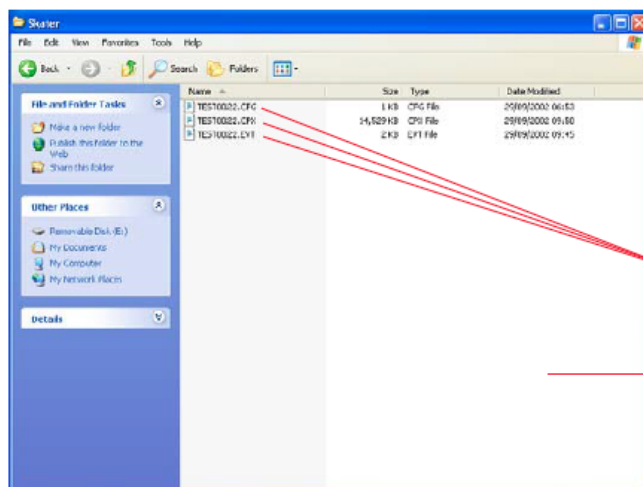


Safety of patient data:

The measuring data are always assigned to the currently selected patient. Before the data are read out in order to ensure the safety of patient data, it must be checked whether time and data of the measuring data belong to the selected patient.

2. Insert Flash Card

When the Flash Card is inserted in the Flash Card Reader, all of the files saved on the Flash Card are displayed. Windows XP indicates the Flash Card Reader as drive "SanDisk Image-Mate E:" (standard installation). For each measurement 3 files are displayed which indicate date and time, size as well as a file name.



For example:

TEST0001.CFG (Config Data Test 1)
TEST0001.CPX (Cardic Data Test 1)
TEST0001.EVT (Event Data Test 1)

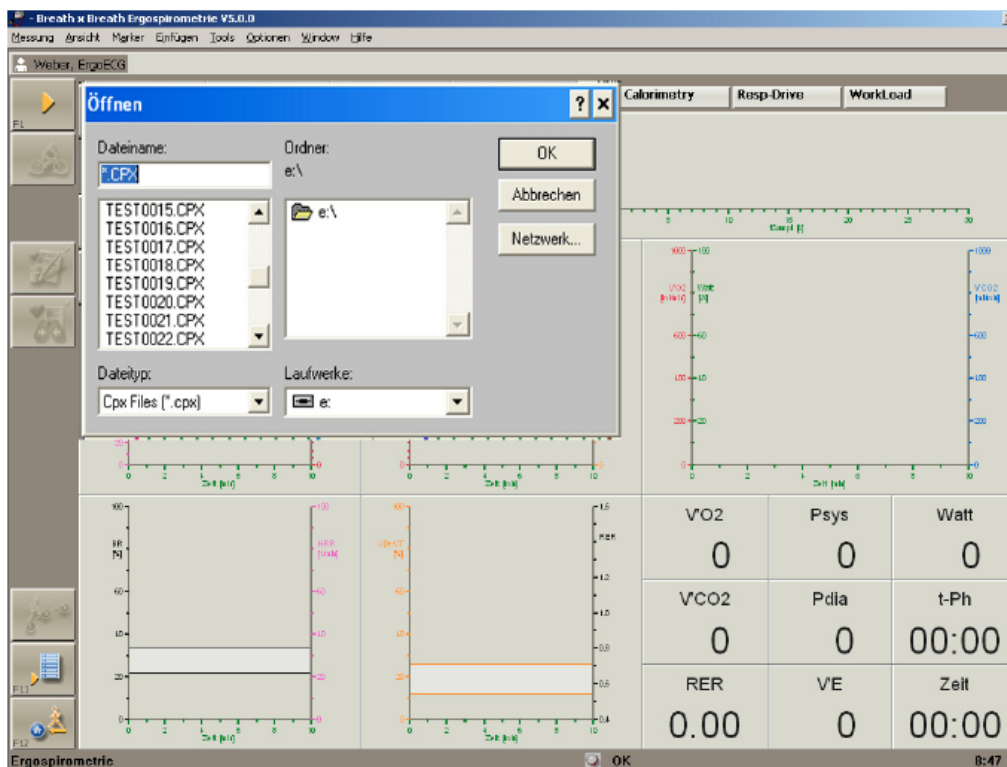
Date and time of measurement

Display of 3 files per measurement in the Windows XP Explorer



3. Read out Flash Card

Select **"Read out Flash Card"** from the **Main group** of the LabManager in order to read out the measuring data. The following appears on the screen:



Select the desired measurement and confirm your selection with **(OK)**. The ergospirometry startup screen appears. Click **(OK)** again.

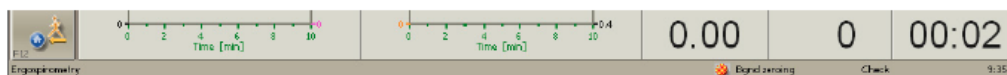


"F1" starts the **"Check"** phase.

Further sequence:

The following sequence is similar to that of an ordinary ergospirometry measurement. More detailed information can be found under **"Ergospirometry"** in this manual. The preset sequence **"Ox-Mobile"** has to be used.

In the status line appears **"Bgnd zeroing"**



and then **"OK"**.



Now measuring data are read out. In the status line appears **"Recording"**.

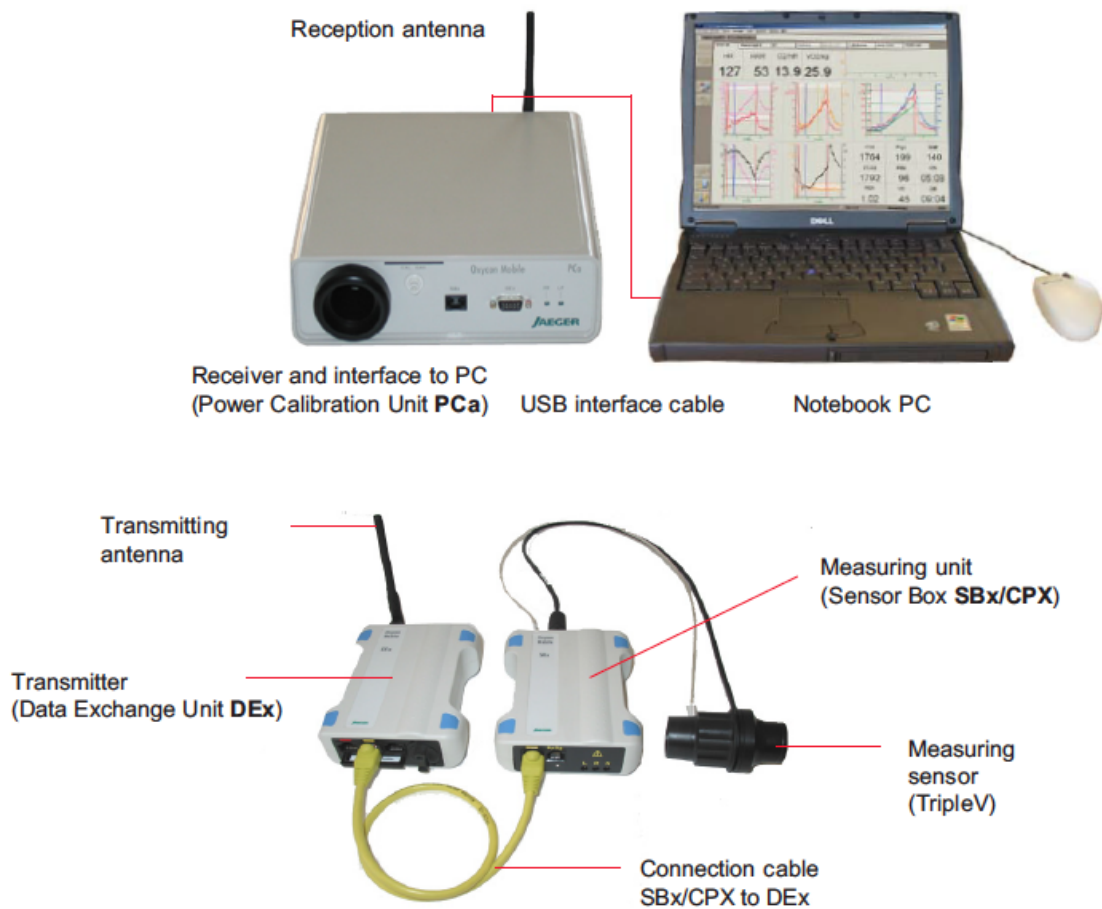


Click **"F12"** to save the recording and end the program.

Notes on using the Flash Card:

- Please observe the manufacturer's instruction manual, which is delivered with the flash card reader.
- The number and the recording time of the measurements, which are to be saved, is limited by the memory capacity of the flash card.
- Only use the recommended flash card, which is available from Cardinal Health. More detailed information can be found under "disposables and Replacement Parts" in the OxyCon Manual.
- If measuring data are assigned to a patient and read out, delete the data from the flash card in order to avoid that data get mixed up later. Specific measurements (or even all of the flash card data) can be deleted in the Explorer program of Windows XP.
- Delete the .CFG, .CPX, and .EVT file of the selected measurements(s). Press the key combination ALT+TAB in order to change from the program "Read out Flash Card" to the Explorer program (and vice-versa).

Additional images and component views:



Insert and Load Battery



In order to operate the **Oxycon Mobile** a lithium-ion battery must be inserted in the DEx unit, first. Two lithium-ion batteries are included in the delivery. The operating time is about 2 hours per battery. Before a measurement is started, it must be ensured that a fully charged battery is inserted. Only lithium-ion batteries (3.6 V, 1500 mAh) which are recommended by **Cardinal Health** must be used.



Battery charger:

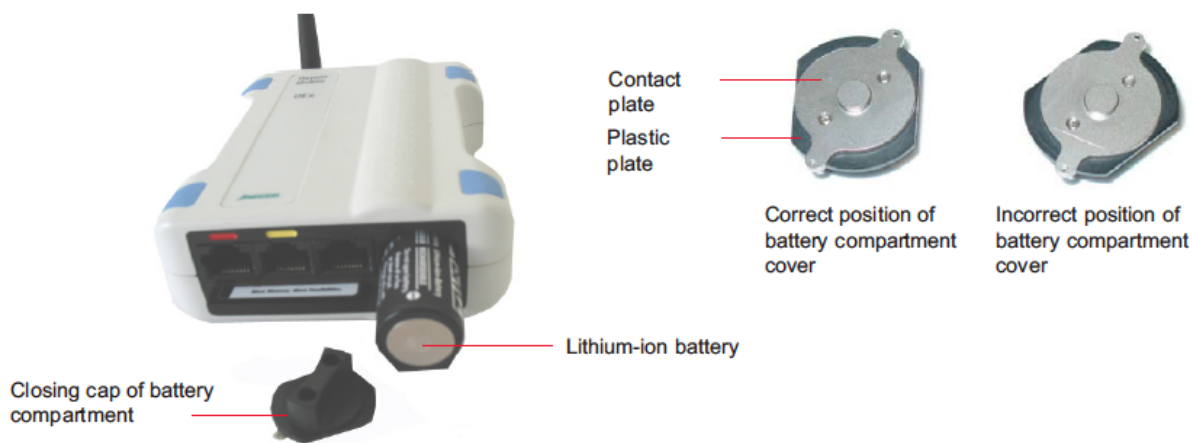
Either one or two batteries at the same time can be charged with the delivered charger. Please note the charger operating manual. Charge the lithium-ion battery only by the charger delivered by **Cardinal Health**. A defective charger has to be replaced by a **Cardinal Health**-released battery charger. See "Disposables and Replacement Parts" in this manual.

The yellow LED indicates the charging process. The battery is completely charged, if the LED stops lighting up.



Inserting and closing the cover:

When the cover is inserted, it must be observed that the contact plate is correctly positioned on the plastic plate. If necessary, rotate the plastic plate by hand.



Battery Exchange during Operating the DEx Unit

When the yellow LED on the DEx unit is blinking or the earphone message: "Battery almost exhausted" is received, the user is asked to change the battery. The battery can be exchanged during operating the DEx unit and also during a measurement.

- Remove the empty battery **without** switching off the DEx unit before.
- Insert new battery.
- Continue the measurement if the new battery is inserted. It is **not** necessary to switch on the DEx unit again.

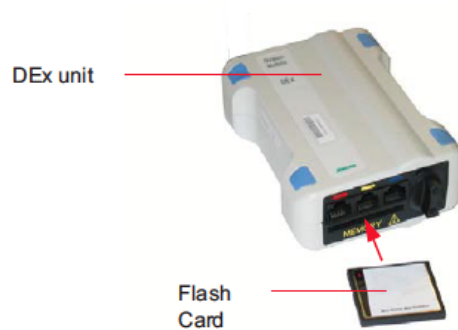


No data are lost when the battery is exchanged!

If, for example, the battery is exchanged during standby, the **Oxycon Mobile** is also in standby after this battery exchange.

Insert Flash Card

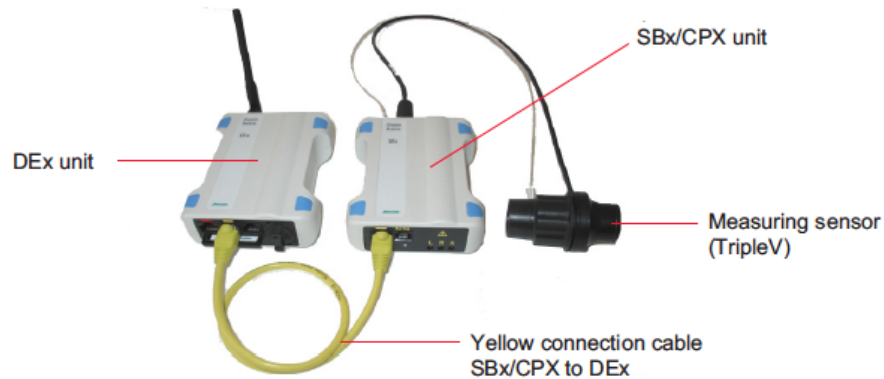
Insert the Flash Card in the DEx unit as shown below.



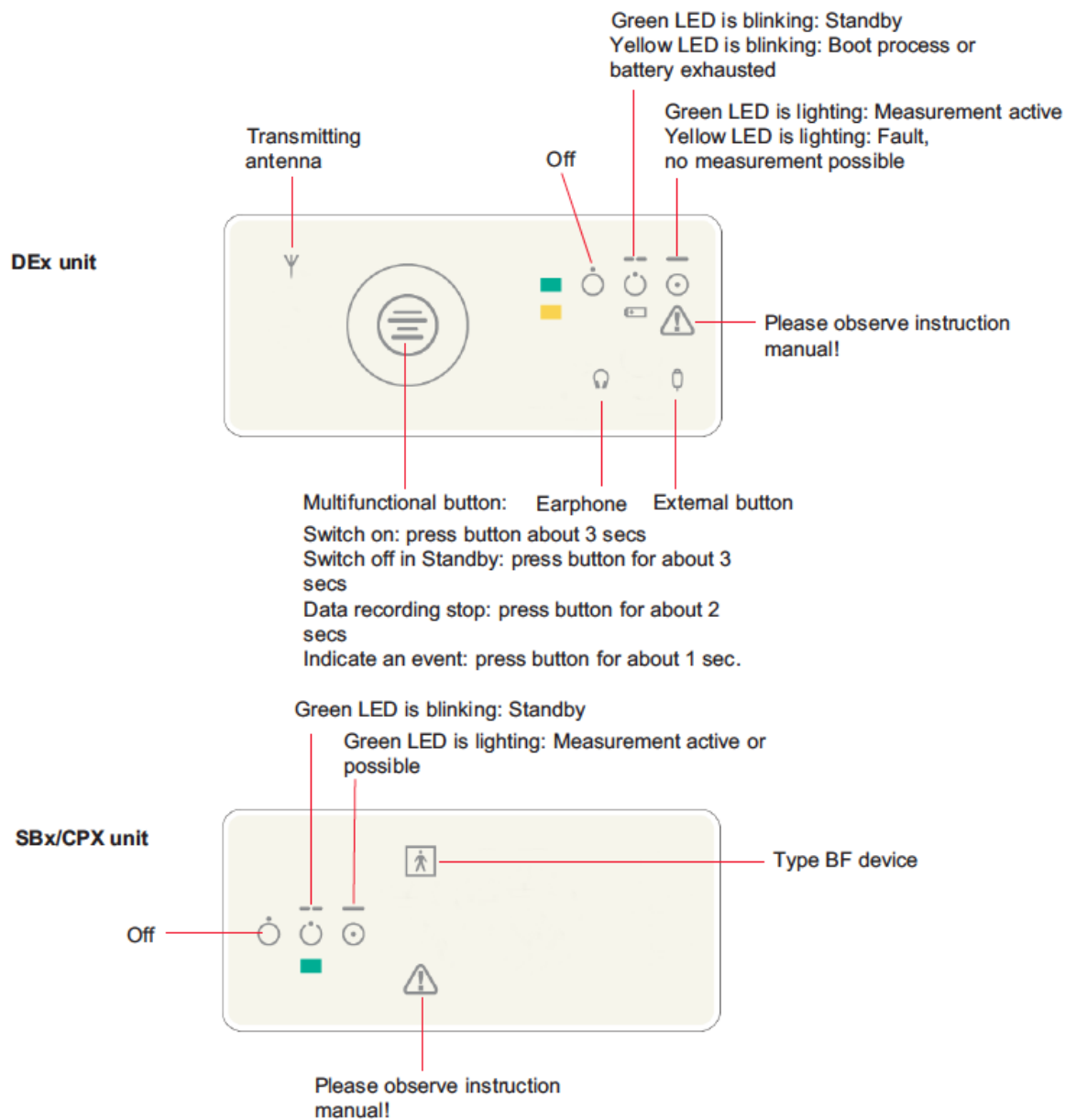
Prior to every measurement an empty/deleted Flash Card has to be inserted.

Switch on/off DEx and SBx/CPX Unit

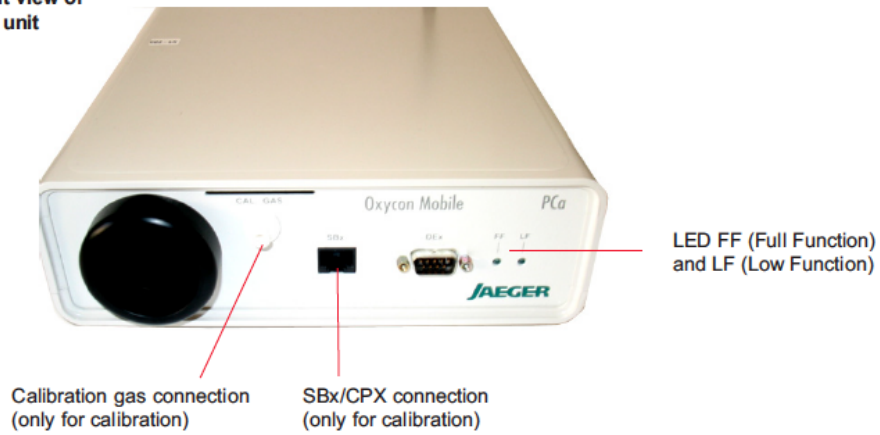
Connect the DEx unit to the SBx/CPX unit via the yellow cable (yellow marked sockets) and connect the TripleV to the SBx unit. Press the multifunctional button for about 3 seconds to switch on the DEx unit. First, the yellow LED on the DEx unit lights up (indicating the boot process). After a few seconds the green LEDs on both units have to blink in order to indicate "Standby". In this "Standby" phase the DEx and SBx/CPX units can also be switched off by pressing the multifunctional button for about 3 seconds.



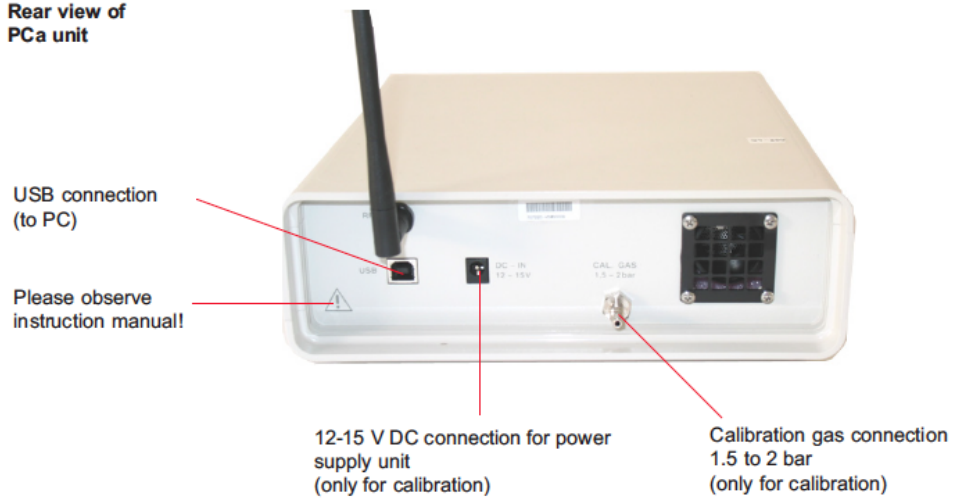
Graphical Symbols



**Front view of
PCa unit**



**Rear view of
PCa unit**



VELOS: PATIENT DATA COLLECTION REPOSITORY.

General Principles:

- Velos eResearch is a secured web-based application, backed-up and supported on site at UM
- The Velos eResearch clinical trials management system provides study teams with a tool to track study patients and their status histories, individual study calendars and progress in completing a protocol, adverse events, and any associated data collection.
- Department administrators can track the financial aspects of performing a protocol and generate invoices to collect reimbursement from sponsors.
- Data Safety and Monitory Boards/Committees can run reports to track compliance with protocol standards
- Facilitates compliance with University processes and policies.
- Ensures strict and controlled access to protected health information (PHI), allowing for patient identifiable information to be stored safely in an electronic format
- Velos eResearch has electronic CRF's that will be used to collect data.
- Source data in 'hard copy' will be forwarded to the lead center for data entry and filing

Directions for accessing and utilizing Velos eResearch:

- Using your web browser, navigate to: <http://velos.miami.edu>
- This will load the login homepage:

The screenshot shows the login page for the University of Miami's CanelD Authentication Service. At the top, there is a green header with the University of Miami logo and the text "CanelD Authentication Service". Below the header, a message states: "You have requested access to Velos which requires University of Miami authentication." The main content area is divided into two sections. On the left, under the heading "Login", there are input fields for "Enter CanelD:" (with an example "-j.doe") and "Password:", followed by a "Login" button. Below these fields is a checkbox labeled "Warn me before logging me in to other sites." and a red warning message: "For security reasons, quit your web browser when you are done accessing services that require CanelD authentication!". On the right, under the heading "Your CanelD Account", there are links for "Change your password", "Change your security question", and "Help Topics". The "Help Topics" section includes links for "First time using CanelD?", "Forgot your CanelD or Password?", "Is your CanelD disabled?", and "More help topics...". At the bottom of the page, there is a small disclaimer: "Be wary of any program or web page that asks you for your username and password. Secure University of Miami web pages that ask you for your username and password will generally have URLs that begin with 'https://caneld.miami.edu'. In addition, your browser should visually indicate that you are accessing a secure page."

- Enter your username and password and click "LOGIN"
- This will load the Velos homepage:

Current Page: Velos eResearch >> Homepage

UHealth UNIVERSITY OF MIAMI MILLER SCHOOL OF MEDICINE

Study Search Patient Search Study Patients Report Central

Search a Study Search ADVANCED SEARCH Account Forms Edit

Last Modified Studies [VIEW ALL STUDIES](#)

	S	P	D	Study Number	Study Title	Study Status
	S	P	D	20100464 - DOD - Nash	Obesity/Overweight in Persons with Early and Chronic SCI: A Randomized Multi-Cen...	Active/Enrolling
	S	D		20110697 - Intramural - Schiff	GS-US-248-0123 A Long Term Follow-up Registry Study of Subjects Who Did Not Achi...	Not Active
	S	P	D	20110696 - Intramural - Schiff	GS-US-248-0122 A Long Term Follow-up Registry for Subjects Who Achieve a Sustain...	Not Active
	S	P	D	20100311 - Intramural - Romanelli	Prospective evaluation of immunohistochemical expression of JCAM-1 in tissue spe...	Active/Enrolling
	S	P	D	20100136 - TACL - Goldberg	A Phase II Study of Clofarabine with Etoposide and Cyclophosphamide in Relapsed/...	Study Completed

My Links [Edit](#)

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Quick Links [Edit](#)

Email Support	yesinfo@med.miami.edu
Patient Management	JChart Shortcut
Support & Training	JM Velos Support
Velos Documents	Velos Glossary

Current User: Eric Poince
System Timezone: (GMT -05:00) Eastern Time (US and Canada)

Message Center [Unread\(0\)](#) [Read\(0\)](#) [Acknowledgements\(0\)](#) [Unread Messages](#)

Name	Study	Text	Request	Permission	Snapshot
				What is a Snapshot	Click on [S] to view the current study snapshot.

- The GREEN tab columns on the left-hand side are the main navigation buttons in Velos
- Clicking on the HOMEPAGE tab will return you to this screen and can reorient you in the system
- A list of all the studies that you have access to will appear
- 'DOD – Nash' study (highlighted yellow) is our study of interest (This should be the only study visible for the Shepherd/Atlanta institution members)
- Selecting the **S** button in the study will load the general study information:

Summary | Versions | Admin Schedule | Study Setup | Notifications | Study Status | Reports | Study Team | Broadcast | Forms

[COPY AN EXISTING STUDY](#)

Study Entered By * [SELECT USER](#)

Principal Investigator [SELECT USER](#)

Study Contact [SELECT USER](#)

☒ Principal Investigator was a major author/initiator of this study?
☐ Investigator Held IND/IDE? IND/IDE #

Study Definition

Study Number * **D** [MORE STUDY DETAILS](#)

Title *

Objective

Summary

Do you want Information in this section to be available to the public? ☐ Yes ☒ No [?](#)

Study Details

Agent/Device

Division

Therapeutic Area * [SELECT DISEASE SITE\(S\)](#)

Disease Site [SELECT SITE 1](#)

Specific Sites [SELECT SITE 2](#)

National Sample Size [LOCAL SAMPLE SIZE](#)

Study Duration

Estimated Begin Date [Select an Option](#)

Do you want Information in this section to be available to the public? ☐ Yes ☒ No [?](#)

Study Design

Phase *

Research Type

Study Scope

Study Type

Study Linked To

Blinding [Select](#)

Randomization

Do you want Information in this section to be available to the public? ☐ Yes ☒ No [?](#)

Sponsor Information

Sponsor Name

If Other

Sponsor Protocol

Sponsor Contact

Sponsor Address

Do you want Information in this section to be available to the public? ☐ Yes ☒ No [?](#)

Keywords

Keywords

Tip: Enter specific words, which will help to search this trial. For Example leukemia,. You can add more than one keyword separated by a ',' (comma)

e-Signature [Submit](#)

- The first tab shown: SUMMARY – is a general description of the study information, details, description, as well as sponsor information
- Selecting the STUDY SETUP tab will load the following page:

- Here you can preview details related to the study arms, study calendars, and associated study forms
 - CRT – Exercise only group
 - CRT + Intervention – Exercise, dietary, and lifestyle group
- The two calendar arms reflect the two study treatment arms, which patients will be assigned to accordingly
- Selecting the STUDY STATUS tab will load the following page:

- This page provides information regarding the organization/institutions that can enroll patients in this study
- The University of Miami is the parent organization or regulatory site – however, is never the organization enrolling patients. It acts as the repository for the study
- VA, UMMG (UM Medical Group), and Shepherd ATL are all listed as patient enrolling sites
- Selecting the STUDY TEAM tab will load the following page:

Current Page: Study >> Team

UHealth UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE

Study Search Patient Search Study Patients Report Central

Summary Versions Admin Schedule Study Setup Notifications Study Status Reports Study Team Broadcast Forms

Study Number: 20100464 - DDD - Nash

Search by Organization: All Search View Super Users with access to this Study

Study Team	Organization	User Name	Role	Access Rights	States	ADD/EDIT STUDY TEAM MEMBER
University of Miami		Alberto Martinez-Arizala	Study Co-investigator	Access Rights	Active C H	Remove from Team
		Mark Nash	Principal Investigator	Access Rights	Active C H	Remove from Team
		Tracie Miller	Study Co-investigator	Access Rights	Active C H	Remove from Team
		Armando Mendez	Study Co-investigator	Access Rights	Active C H	Remove from Team
		Gabriel Somarriba	Study Assistant	Access Rights	Active C H	Remove from Team
		Kevin Jacobs	Study Co-investigator	Access Rights	Active C H	Remove from Team
		Patricia Burns	Study Coordinator	Access Rights	Active C H	Remove from Team
		Kimberly Anderson	Study Co-investigator	Access Rights	Active C H	Remove from Team
		Lawrence Brooks	Study Co-investigator	Access Rights	Active C H	Remove from Team
		Luisa Betancourt Chaparro	Study Coordinator	Access Rights	Active C H	Remove from Team
		Richard Morris	Data Manager	Access Rights	Active C H	Remove from Team
		Gregory Bigford	Study Coordinator	Access Rights	Active C H	Remove from Team
VA			Local Sample Size: 20	Track Study Status	Active C H	Remove from Team
USMC			Local Sample Size: 40	Track Study Status	Active C H	Remove from Team
Shepherd Medical Center (Atlanta)			Local Sample Size: -	Track Study Status	Active C H	Remove from Team
		Deborah Backus	Study Co-investigator	Access Rights	Active C H	Remove from Team
		Carlyn Kappy	Study Coordinator	Access Rights	Active C H	Remove from Team
		Kathy Krieger	Study Coordinator	Access Rights	Active C H	Remove from Team

Current User: Eric Ponce
System Timezone: (GMT-05:00) Eastern Time (US and Canada)

- All personnel with access to the study are listed, and appear under their corresponding institutional affiliation
- The Shepherd ATL study team is highlighted in yellow

SELECT HOMEPAGE FROM THE GREEN NAVIGATION BAR TO RETURN

Current Page: Velox eResearch >> Homepage

UHealth UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE

Study Search Patient Search Study Patients Report Central

Search a Study Search ADVANCED SEARCH Account Forms Edit

Last Modified Studies

Study Number	Study Title	Study Status
20100464 - DDD - Nash	Obesity/Overweight in Persons with Early and Chronic SCI: A Randomized Multi-Cen...	Active/Cancelled
20110697 - Intramural - Schiff	GS-US-248-0123 A Long Term Follow-up Registry Study of Subjects Who Did Not Ach...	Not Active
20110696 - Intramural - Schiff	GS-US-248-0122 A Long Term Follow-up Registry for Subjects Who Achieve a Sustain...	Not Active
201100311 - Intramural - Romanelli	Prospective evaluation of immunohistochemical expression of ICAM-1 in tissue spe...	Active/Cancelled
201100136 - TACL - Goldberg	A Phase II Study of Clofarabine with Etoposide and Cyclophosphamide in Relapsed/...	Study Completed

My Links Edit

Quick Links Edit

Email Support	xxinfo@med.miami.edu
Patient Management	UChart.UHealth
Support & Training	UM Velox Support
Velox Documents	Velox Glossary

Message Center: Unread(V) Read(V) Acknowledgement(V) Unread Messages Text Request Permission Snapshot

What is a Snapshot Click on to view the current study snapshot.

Current User: Eric Ponce
System Timezone: (GMT-05:00) Eastern Time (US and Canada)

- Selecting the D button in the study will load additional study document and details:

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

Welcome Gregory Bigford
The following sections contain additional information available for this protocol. Please note that some links to documents may require you to enter your eProst login credentials.

Division: Neurosurgery
Study number: 20100464 - DOD - Nash
Current study status: Active/Enrolling on 08/17/2011
InfoEd number: 51320

Account number: 66739P
Package ID: N/A
Package type: N/A
Plan code: N/A

Documents Abstract/Study Design Eligibility Criteria Drugs, Biologics & Supplements Devices

Approved Consent Forms

20100464_ADV_IRBApp081710_FLYER_ENG.doc	0.01
20100464_ICF_IRBApp06242011_UM_ENG.doc	0.02

Sponsor Protocols

Final Protocol.pdf	0.01
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InfoEd Documents

InfoEd Number	Category	Document Name	File Name	Uploaded By	Uploaded Date
<ul style="list-style-type: none"> Content partially provided by eProst, the University of Miami Electronic Protocol Submission and Tracking System, which is maintained by the Human Subjects Research Office. Please note that clicking on a document link that is provided by eProst will require your eProst login credentials. 					

- The first tab shown: DOCUMENTS – contains direct links to all approved IRB and HIPAA documents, as well as the sponsor protocol
- Selecting the ABSTRACT/STUDY DESIGN tab will load the following page:

UHealth
UNIVERSITY OF MIAMI HEALTH SYSTEM

Welcome Gregory Bigford
The following sections contain additional information available for this protocol. Please note that some links to documents may require you to enter your eProst login credentials.

Division: Neurosurgery
Study number: 20100464 - DOD - Nash
Current study status: Active/Enrolling on 08/17/2011
InfoEd number: 51320

Account number: 66739P
Package ID: N/A
Package type: N/A
Plan code: N/A

Documents **Abstract/Study Design** Eligibility Criteria Drugs, Biologics & Supplements Devices

Abstract Specific Aim

The problem of obesity addressed by this proposal represents a serious and worsening health hazard for persons with spinal cord injuries (SCI). Military directives and public policy have brought this problem to the forefront of health priorities. To address these directives and policies, the overarching study objective is to reduce health hazards from an overweight/obese body habitus and co-morbid cardiometabolic disorders in people with SCI, and to improve their life quality. The proposal describes a four-year multi-center randomized clinical trial (RCT) conducted at 2 SCI rehabilitation research centers and two Veterans Affairs Medical Centers. The study is modeled after the Diabetes Prevention Program (DPP), an NIH-sponsored 27-center RCT that reported a sustained 7% body weight reduction in pre-diabetic individuals accompanied by a 58% decrease in progression to type-2 diabetes. The lifestyle intervention approach incorporating diet, exercise, and behavioral adjustments was more effective than pharmacotherapy, benefited both genders and persons of all races, and has lasted 10 years after initiation.

The study plan will enroll 80 persons with SCI who are overweight/obese and have fasting atherogenic dyslipidemia and dysglycemia. A Data Safety Management Board will oversee the trial. Interventions will include 6 months of structured lifestyle intervention incorporating education, exercise, diet, and behavioral support. A second arm will test benefits of exercise alone while controlling for investigator contact. Multiple baselines tested before intervention will serve as a treatment control.

Exercise will include a six-month circuit resistance training program already established as effective in fitness attainment for persons with paraplegia and tetraplegia. Dietary intervention over the same period will balance caloric expenditure measured by indirect calorimetry and food intake, the latter coming from a Mediterranean style diet having effectiveness established in the DPP for durable weight loss and diabetes prevention. The investigators and personal lifestyle coaches will then shape and follow client-specific exercise and diet programs to be conducted for 12 months in the home or community-based centers. Behavioral approaches will include a 16-week training curriculum presented in both small groups and with the lifestyle coaches. Other behavioral approaches will include customized trial information booklets, performance incentives, outcome challenges between centers, and use of the VA Telehealth system for performance tracking, compliance assessment, and motivational support.

Study specific aims and their accompanying hypotheses will test effects of intervention on: 1) reducing body weight and radiographically-derived body fat, 2) improving fitness as assessed by endurance, strength, and anaerobic power, 3) reducing risks of fasting dyslipidemia, post-prandial lipemia, and insulin resistance, and 4) enhancing perceived health-related quality of life. Data will be analyzed by Multivariate analysis with repeated measures. Ancillary testing will investigate effects of intervention on the whole body oxidation of fat at rest and following food intake, and examine the relationship between dietary intake and caloric expenditure at the beginning and the end of the 18 month study. The primary trial goal pays fidelity to the DPP by targeting sustained loss of 7% of body weight, a proven countermeasure for prevention of diabetes.

Positive results of training will represent the first evidence-based randomized multi-center trial of sustained weight loss in persons with SCI military or civilian. In the near term the data will provide evidence needed to initiate health reform of military and non-military constituencies with disability. The information will also underwrite changes in dietary support of newly injured persons. The information will further provide a roadmap for clinicians to institute client-centered programs of health planning and recovery. As the extension phase will test both home and community-based programs, deployment to wider military constituencies of persons with SCI can be achieved through VA Community Outpatient Clinics. The trial can also become a roadmap to weight and disease management experience by persons with physical impairments other than SCI.

- Here you can preview details regarding the study abstract, specific aims, methodological rationale, and statistical design
- Selecting the ELIGIBILITY CRITERIA tab will load the following page:

Exclusion Criteria

Study candidates will be excluded from study because of: structured exercise conditioning for recreation or competition within 6 months of study entry; defined diet involving caloric restriction or nutrient modification; weight loss or gain of 5% within the preceding 6 months; surgery within 6 months; pressure ulcer within 3 months; upper limb pain that limits exercise; recurrent acute infection or illness requiring hospitalization or IV antibiotics; pregnancy; previous MI or cardiac surgery; 6 month history of glucose-lowering and lipid-lowering drug therapy; Type I or II diabetes (by WHO criteria); and daily intake of vitamin supplements exceeding 100% RDA.

Further, individuals will be excluded who present with a disorder or condition that may affect the conduct of the trial, such as traumatic brain injury, substance abuse/dependence, major psychiatric conditions, or participation in another trial. The following medications and drug therapies will disqualify subjects from participating: beta-adrenergic antagonists, maintenance alpha-blockers, Methyllopa, thiazide and loop diuretics, parasympatholytic agents, zinc, estrogen/hormone replacement therapy excluding oral contraceptives, and insulin-sensitizing drugs (Sulfonylureas, Biguanides, Thiazolidinediones, Glitnides, -glucosidase, GLP-1 analogues, and DPP-IV inhibitors), and lipid-altering agents (HMG-CoA Reductase Inhibitors, Niacin [Intermediate or Extended-Release], Fibric Acid Derivatives, Bile Acid Sequestrates, and Intestinal Uptake Blockers) As

Bafoenen can influence IGF-1 levels, 157 any change in drug administration before or during training will be noted. Blood sampling times will be altered in menstruating women to test during the follicular menstrual phase (cycle days 5-10), as is recommended. The diet being undertaken nor exercise are contraindicated during early-stage pregnancy, although women who become pregnant will be instructed to advise the Site PIs or physicians. They will then be discharged from the trial. Women who are post-partum must wait 6 months after delivering to enter the study a criterion of the DPP.

We will exclude any individuals with a diagnosis of diabetes if after 3 months of intervention the following diagnostic criteria of the ADA are not satisfied:

- 1) Fasting Blood Glucose 126 mg/dL after a fast of 8+ hours, OR
- 2) Symptoms of hyperglycemia (i.e., polyuria, polydipsia, and unexplained weight loss) and a casual plasma glucose 200 mg/dL, OR
- 3) 2-hour plasma glucose during an OGTT using a glucose load of 75g.

In the absence of unequivocal hyperglycemia, these criteria will be confirmed by repeat testing on a different day (Per ADA criteria). Should the participant still satisfy criteria for diagnosis of diabetes they will be seen by the study physician, discharged from the trial, and referred for immediate treatment of their condition.

Inclusion Criteria

Participants will include 64 men and women aged 18-65 years with SCI (AIS A-C) at the CS-L1 levels for more than 1 year. The International Standards for Neurological Classification of SCI (ASIA/ISCoS) will serve as benchmarks for subject classification. A physician-rater experienced in these procedures will classify subjects upon study entry.

Persons from all ethnic and racial groups will be enrolled. We will seek a gender distribution in proportion to population representation of persons with SCI (~80% male). Genders and persons with paraplegia/tetraplegia will be matched in equal numbers within study arms. After being provided with the study privacy practices, and HIPAA certification indicating available protections, participants will undergo informed consent procedures approved by one of four oversight Institutional Review Boards (IRBs): University of Miami Miller School of Medicine (UM-MSOM), the Shepherd Center, the Veterans Affairs Medical Center-Miami, or the Veterans Affairs Medical Center-Atlanta.

Study candidates will be screened for the following entrance inclusions:






- 1) BMI $\geq 22 \text{ kg/m}^2$,
- 2) fasting dyslipidemia (HDL-C 40 mg/dL or TG 150 mg/dL) by NCEP ATP III Guidelines, and
- 3) impaired fasting glucose ($\geq 100 \text{ mg/dL}$) by 2006 ADA criteria.



We have adopted these criteria to: 1. create a larger capture of participants with multiple risk clusters, 2. identify component risks of cardiometabolic syndrome (by NCEP ATP III Guidelines) that are amenable to exercise and dietary intervention, 42. 3. Avoid 'baseless effects' of testing that might occur in persons with normal fasting blood glucose, and 4. Exclude persons having more serious conditions (i.e., diabetes mellitus), where ethical commitments to patients and guideline driven medical standards would require medical treatment instead of lifestyle intervention. BMI will be calculated as weight (kg)/height (m)² using height measured during recumbency on a mat. A BMI of 22 kg/m² has recently been published as a better criterion than the previous 23 kg/m² criterion for identifying obesity after SCI. Weight will be measured on a calibrated scale.

- Here you can preview details regarding inclusion and exclusion criteria that have been established for the study

SELECT HOMEPAGE FROM THE GREEN NAVIGATION BAR TO RETURN

Current Page: Velos eResearch >> Homepage

Search a Study [Search](#) [ADVANCED SEARCH](#) [Account Forms](#) [Edit](#)

Last Modified Studies [VIEW ALL STUDIES](#)

Study Number			Study Title	Study Status
S	P	D	20100464 - DOD - Nash	Active/Enrollals
S	D	D	2010697 - Intramural - Schiff	Not Active
S	D	D	2010696 - Intramural - Schiff	Not Active
S	P	D	20100311 - Intramural - Romanelli	Active/Enrollals
S	P	D	20100136 - TACL - Goldberg	Study Completed


My Links [Edit](#)

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Current User: Eric Ponce
System Timezone: GMT-05:00 Eastern Time (US and Canada)

Message Center [Unread\(0\)](#) [Read\(0\)](#) [Acknowledgements\(0\)](#) [Unread Messages](#)

Name	Study	Text	Request	Permission	Snapshot
What is a Snapshot Click on  to view the current study snapshot.					

- Selecting the **P** button in the study will load the following page:

Current Page: Manage Patients >> Study Patients

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Study Search Patient Search Study Patients Report Central

Homepage Personalize Account Manage Protocols Library Manage Patients Budget Milestones Report Central Dashboards Ad-Hoc Queries Help Logout

Patient Search Enrolled

Search By

Patients on Study: 20100464 - DOD - Nash Organization: All Last Visit: Enrolled On: ALL Next Visit: ALL Patient ID: Patient Study ID: Patient Status: All Exclude patients not currently Enrolled Search

Enter Screening/Enrollment details SELECT AN EXISTING PATIENT ADD A NEW PATIENT

Page 1 of 0 Rows per page 5 Showing 1 - 0 of 0 SAVE VIEW SAVE(D) SEARCH EXPORT TO EXCEL

Study Number	Patient ID	Enrolling Site	F Name	Pt. Study ID	L Name	Enrolled	Last Visit	Next Due	Visit Status	Pt. status	Enrolled By	Assigned To	Physician	Treatment Organization	Treatment Arm	AE Count	SAE Count
No records found.																	

- Selecting MANAGE PATIENTS from the BLUE navigation bar will load the following page:

Current Page: Manage Patient >> New

UHealth UNIVERSITY OF MIAMI HEALTH SYSTEM UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE

Study Search Patient Search Study Patients Report Central

Homepage Quick View Personalize Account Manage Account Manage Protocols Library Manage Patients New Open Budget Milestones Report Central Dashboards Ad-Hoc Queries Help Logout

Patient ID (CLICK TO ACCESS PATIENT LOOKUP) First Name Last Name Date of Birth * Gender Primary Ethnicity Primary Race

Select an Option Select an Option Select an Option

Registration Details

Organization * University of Miami MRN Provider Select User Survival Status * Alive Date of Death Cause of Death Select an Option Specify Cause

Specify groups/departments with access to edit patient's demographics. If blank, all groups have access

Select a study to enter screening/enrollment details for this patient: Select an Option

e-Signature Submit

Current User: Eric Ponce System Timezone: GMT-05:00 Eastern Time (US and Canada)

- Selecting NEW will load a patient entry page automatically
- Clicking on the link CLICK TO ACCESS PATIENT LOOKUP will open a new window:

UHealth Patient Lookup Welcome, Gregory Bigford

How to use this tool.

1. Search for a patient	2. Verify patient	3. Attach patient to your study
MRN: First Name: Last Name: Year of Birth: Clear Search	Can't find patient	

- The Shepherd ATL group will not have patients in the UHealth system or any associated institutions
- Selecting CAN'T FIND PATIENT from 2. Verify Patient will allow addition of new patients:

1. Search for a patient	2. Verify patient	3. Attach patient to your study
MRN: <input type="text"/> First Name: <input type="text"/> Last Name: <input type="text"/> Year of Birth: <input type="text"/> <input type="button" value="Clear"/> <input type="button" value="Search"/>	First Name* <input type="text"/> Last Name* <input type="text"/> D.O.B.* <input type="text"/> Gender* <input type="text"/> Ethnicity* <input type="text"/> Race* <input type="text"/> <input type="button" value="Can't find patient"/> <input type="button" value="Use this patient"/>	

- Add all the necessary patient information
- Clicking on the USE THIS PATIENT button will then allow you to attach this patient to the study:

1. Search for a patient	2. Verify patient	3. Attach patient to your study
MRN: <input type="text"/> First Name: <input type="text"/> Last Name: <input type="text"/> Year of Birth: <input type="text"/> <input type="button" value="Clear"/> <input type="button" value="Search"/>	First Name* Gregory Last Name* Bigford D.O.B.* 08/19/2011 Gender* Male Ethnicity* Unknown Race* Unknown <input type="button" value="Can't find patient"/> <input type="button" value="Use this patient"/>	Study* 20100464 - DOD - Nash Enrolling Site* VA Study Details More Title: Obesity/Overweight in Persons with Early and Chronic SCI: A Randomized Multi-Center Controlled Lifestyle Intervention Division: Neurosurgery Pt: Nash, Mark Site Sample Size (Accrued / Total sample size): (0/20) eSignature* <input type="text"/> <input type="button" value="Submit"/>


- Enter DOD – NASH in the study box
- The study will appear in a drop down menu, select the study
- Enter the appropriate enrolling site from the drop down menu (ie Shepherd ATL)
- Your e-signature is required to save this patient to the study

CRF forms in VELOS eResearch attached to the study:

Screening Form:

Form Name: Screening Form (Nash Study)

Screening Form

Data Entry Date* 

Patient Code*

Height (Meters)

Body Mass (kg)

Gender ☐ Male
☐ Female
☐ Other

Veteran ☐ Yes
☐ No

Inclusion Criteria

<input type="radio"/> C5	<input type="radio"/> C6
<input type="radio"/> C7	<input type="radio"/> T1
<input type="radio"/> T2	<input type="radio"/> T3
<input type="radio"/> T4	<input type="radio"/> T5
<input type="radio"/> T6	<input type="radio"/> T7
<input type="radio"/> T8	<input type="radio"/> T9
<input type="radio"/> T10	<input type="radio"/> T11
<input type="radio"/> T12	<input type="radio"/> L1

AIS (Injury Level)

Injury Duration Greater than a year? ☐ Yes
☐ No

Age between 18 - 65 yrs old? ☐ Yes
☐ No

Body Mass Index? ☐ Yes
☐ No

Body Mass Index (Kg/Msq)

Fasting Dislipidemia (HDL)? ☐ Yes
☐ No

Fasting Dislipidemia HDL (mg/dL)

Fasting Dislipidemia (Triglyceride)? ☐ Yes
☐ No

Fasting Dislipidemia -Triglyceride (mg/dL)

Impaired Fasting Glucose? ☐ Yes
☐ No

Impaired Fasting Glucose (mg/dL)

Exclusion Criteria

Structured exercise conditioning within 6 months of study entry? ☐ Yes ☐ No

Defined diet involving caloric restriction or nutrient modification? ☐ Yes ☐ No

Weight loss/gain of 5% within 6 months of study entry? ☐ Yes ☐ No

Surgery within 6 months of study entry? ☐ Yes ☐ No

Pressure ulcer within 3 months of study entry? ☐ Yes ☐ No

Upper limb pain that limits exercise? ☐ Yes ☐ No

Recurrent acute infection/illness requiring hospitalization of IV antibiotics? ☐ Yes ☐ No

Pregnant? ☐ Yes ☐ No

Previous MI or cardiac surgery? ☐ Yes ☐ No

6 month history of glucose-lowering and/or lipid-lowering drug therapy? ☐ Yes ☐ No

Type I OR Type II diabetes? ☐ Yes ☐ No

Daily intake of vitamin supplementation exceeding 100% RDA? ☐ Yes ☐ No

Contraindicated disorder/condition (Traumatic brain injury)? ☐ Yes ☐ No

Contraindicated disorder/condition (Substance abuse/dependence)? ☐ Yes ☐ No

Contraindicated disorder/condition (Psychiatric condition)? ☐ Yes ☐ No

Contraindicated drug therapy (β-adrenergic antagonists)? ☐ Yes ☐ No

Contraindicated drug therapy (Maintenance α-blockers)? ☐ Yes ☐ No

Contraindicated drug therapy (Methylodopa)? ☐ Yes ☐ No

Contraindicated drug therapy (Thiazide and loop diuretics)? ☐ Yes ☐ No

Contraindicated drug therapy (Parasympatholytics)? ☐ Yes ☐ No

Contraindicated drug therapy (Zinc)? ☐ Yes ☐ No

Contraindicated drug therapy (Estrogen/hormone replacement therapy)? ☐ Yes ☐ No

Contraindicated drug therapy (Insulin-sensitizing drugs)? ☐ Yes ☐ No

Contraindicated drug therapy (Lipid-altering agents)? ☐ Yes ☐ No

Fasting Blood Glucose? ☐ Yes ☐ No

Symptoms of Hyperglycemia? ☐ Yes ☐ No

Plasma Glucose during OGTT? ☐ Yes ☐ No

Fasting Blood Glucose (mg/dL)

Casual Plasma Glucose (mg/dL)

Plasma Glucose after OGTT (mg/dL)

Form Status *

Work In Progress

e-Signature *

Anthropometric Form I:

Form Name: Anthropometric Data (Nash Study)

Body Mass

Data Entry Date* 

Body Mass (kg)

Form Status* e-Signature*

Anthropometric For II:

Form Name: Anthropometric Data II (Nash Study)

Body Mass

Data Entry Date* 

Body Mass (kg)

Body Composition

Lean Mass (%)

Fat Mass (%)


Form Status* e-Signature*

- These forms are attached to different events/visits, depending on what data is being collected at that time
- This ensures forms attached to various events only capture data as dictated by the study design

Blood Testing Form:

Form Name: Blood Testing (Nash Study)

Section 1

Data Entry Date* 

Total Cholesterol (mg/dL)

High Density Lipoprotein (mg/dL)

Low Density Lipoprotein (mg/dL)

Triglycerides (mg/dL)

Insulin Resistance

Global CVD risk (TC:HDL)

Global CVD risk (LDL:HDL)


TG Response Curve

Form Status* e-Signature*

Fitness Attributes Form:

Form Name: Fitness Attributes (Nash Study)

Fitness Attributes

Data Entry Date* 

Volume of Oxygen Consumption (VO2 - L/min)

Total Energy Expenditure (TEE - kCal/min)

Carbohydrate Oxidation (CHO - g/min)

Fat Oxidation (FO - g/min)

Power Peak (W)

Power Mean (W)

Repetition Maximum

Military Press (kg)

Horizontal Rows (kg)

Pec dec (kg)

Preacher Curls (kg)

Latissimus Pull-Downs (kg)

Seated Dips ? Rickshaw? (kg)

Form Status* e-Signature*

SF-36 Form:

Form Name: SF-36 Your Health and Well-Being v2

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey!

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

Data Entry Date*

1. In general, would you say your health is:*

Excellent	Very Good	Good	Fair	Poor
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

2. Compared to one year ago, how would you rate your health in general now?*

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Lifting or carrying groceries*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Climbing several flights of stairs*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Climbing one flight of stairs*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. Bending, kneeling, or stooping*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g. Walking more than a mile*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h. Walking several blocks*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i. Walking one block*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
j. Bathing or dressing yourself*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
a. Cut down on the amount of time you spent on work or other related activities*	<input type="radio"/>	<input type="radio"/>
b. Accomplished less than you would like*	<input type="radio"/>	<input type="radio"/>
c. Were limited in the kind of work or other activities*	<input type="radio"/>	<input type="radio"/>
d. Had difficulty performing the work or other activities (for example, it took extra effort)*	<input type="radio"/>	<input type="radio"/>

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
a. Cut down on the amount of time you spent on work or other related activities*	<input type="radio"/>	<input type="radio"/>
b. Accomplished less than you would like*	<input type="radio"/>	<input type="radio"/>
c. Didn't do work or other activities as carefully as usual*	<input type="radio"/>	<input type="radio"/>

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?*

Not at all	Slightly	Moderately	Quite a bit	Extremely
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Cont'd...

7. How much body pain have you had during the past 4 weeks?*

None ☐ Very mild ☐ Mild ☐ Moderate ☐ Severe ☐ Very Severe ☐

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all ☐ A little bit ☐ Moderately ☐ Quite a bit ☐ Extremely ☐

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much time during the past 4 weeks:

	All of the time	Most of the time	A Good bit of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of pep?*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Have you been a very nervous person?*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Have you felt so down in the dumps that nothing could cheer you up?*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Have you felt calm and peaceful?*	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Did you have a lot of energy?*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. Have you felt downhearted and blue?*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g. Did you feel worn out?*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h. Have you been a happy person?*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i. Did you feel tired?*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc)?

All of the time ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time ☐

11. How TRUE or FALSE is each of the following statements for you?

a. I seem to get sick a little easier than other people*	Definitely true <input type="radio"/>	Mostly true <input type="radio"/>	Don't Know <input type="radio"/>	Mostly false <input type="radio"/>	Definitely false <input type="radio"/>
b. I am as healthy as anybody I know*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. I expect my health to get worse*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. My health is excellent*	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

The following calculations are computed mean scores (0-100 scale) for all sf36 subscales. Higher scores indicate better functioning on all subscales.

Calculate

Physical functioning

Role limitations due to phys health problems

Role limitations due to emotional health problems

Energy/Fatigue

Emotional well being

Social functioning

Pain

General health

Physical Composite

Standardized Physical Subscale

Mental Composite

Standardized Mental Subscale

THANK YOU FOR COMPLETING THESE QUESTIONS!

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(SF-36_{v2} Standard, US Version 2.0)

Form Status* e-Signature*

Reporting Data:

- Reports can be designed by navigating from the homepage:

The screenshot shows the Velos eResearch homepage. The browser address bar displays the URL: <https://velos.med.miami.edu/eres/jsp/myHome.jsp?srcmenu=tdMenu8aritem1>. The page features a left-hand navigation menu with options: Homepage, Personalize Account, Manage Protocols, Library, Manage Patients, Budget, Milestones, Report Central, Dashboards, Ad-Hoc Queries (highlighted with a red arrow), Help, and Logout. The main content area includes a 'Search a Study' section with a search bar and a 'Search' button. Below this is a table titled 'Last Modified Studies' with columns for Study Number, Study Title, and Study Status. A single study is listed: 20100464 - DOD - Nash, Obesity/Overweight in Persons with Early and Chronic SCI: A Randomized Multi-Cen..., with status 'Active/Enrolling'. There are also sections for 'My Links' and 'Quick Links' with various utility links. At the bottom, a 'Message Center' shows unread messages and a 'Snapshot' section with a link to view the current study snapshot.

- Selecting AD HOC QUERIES from the BLUE navigation bar will load the following page:

The screenshot shows the 'Ad-Hoc Query >> Saved Report Templates' page. The browser address bar displays the URL: <https://velos.med.miami.edu/eres/jsp/dynrepbrowse.jsp?pagenum=1>. The left-hand navigation menu is the same as the previous page, with 'Ad-Hoc Queries' highlighted. The main content area has a search bar and a 'Search' button. Below the search bar is a table with columns: Display, Report Template Name, Created By, Shared with, Report Type, Study, Copy, Filters, and Delete. The table is currently empty, with the message 'No Matching Ad-Hoc Queries Found' displayed below it. A red arrow points to the 'CREATE REPORT' button in the top right corner of the main content area.

- Here you have the option to select your study (DOD – NASH) and CREATE REPORT:

Current Page: Ad-Hoc Query >> Report Type

UHealth UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE

Study Search Patient Search Study Patients Report Central

Select Report Type >> Select Fields >> Filter Criteria >> Sort Criteria >> Preview & Save Next

Select Report Type

Report Type: Patient

Select Patient Population

☐ All Patients
☒ Patients on a Study
☐ Specific Patient

Select Study: 20100464 - DOD - Nash

Select a Patient

Select Form(s)

Form Name: [Select/Search Form](#)

Search Forms with fields Where Field ID: Contains:

Available Tables

Adverse Events;All Patient Labs;Demographics;More AE Details;More Pat Details;Pat Study Form Query;Pat Study Specimens;Patient Labs;Patient Orgs;Patient Protocols;Patient Schedule;Patient Specimens;Patient Study Stat;Treatment Arm

If one or more forms are selected, the data from Available Tables will be displayed only for those patients/studies that have data entered in the selected Forms(s).

Current User: Gregory Bigford
 System Timezone: (GMT-05:00) Eastern Time (US and Canada)

- Select PATIENT from the drop down box for REPORT TYPE
- Select PATIENTS ON STUDY under PATIENT POPULATION
- Ensure that DOD – NASH is selected from the drop down box
- Click on the link to SELECT/SEARCH FORM to search for the form(s) data desired for reporting
- The following window will appear:

Lookup

Submit Close

☒ Anthropometric Data (Nash Study)
☒ Blood Testing (Nash Study)

Form Browser

Search: Entire Lookup All Contains Search Reset/Sort

Filter Criteria: None

1 to 8 of 8 Record(s) Select All Displayed Remove Selected Record

	FORM NAME	DESCRIPTION	LINKED TO	FORM STATUS
Select	Anthropometric Data (Nash Study)	Visit 1,3,4,5,6,7,9	Patient (Specific Study)	Active
Select	Anthropometric Data II (Nash Study)	Visit 2,8,10	Patient (Specific Study)	Active
Select	Blood Testing (Nash Study)	-	Patient (Specific Study)	Active
Select	Case	Case number and information assigned by IDX to this patient on a this study.	Patient (All Studies - Restricted)	Deactivated
Select	Fitness Attributes (Nash Study)	-	Patient (Specific Study)	Active
Select	SF-36 Your Health and Well-Being v2	-	Patient (Specific Study)	Active
Select	Screening Form (Nash Study)	-	Patient (Specific Study)	Active
Select	Unscheduled Event Form	Captures items related to an unscheduled event, visit that was redone, or AE related charges that need to be captured. When saved, this form is transmitted to the UM CRRC.	Patient (All Studies - Restricted)	Active

1 to 8 of 8 Record(s)

- Select the form(s) desired for reporting in the lower half of the window
- They will appear CHECKED in the upper half of the window (yellow box)
- Select SUBMIT to return to the previous report window:

Current Page: Ad-Hoc Query >> Report Type

UHealth UNIVERSITY OF MIAMI HEALTH SYSTEM UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE

Study Search Patient Search Study Patients Report Central

Homepage Personalize Account Manage Protocols Library Manage Patients Budget Milestones Report Central Dashboards Ad-Hoc Queries Help Logout

Select Report Type >> Select Fields >> Filter Criteria >> Sort Criteria >> Preview & Save Next

Select Report Type

Report Type Patient

Select Patient Population

☐ All Patients
☒ Patients on a Study
☐ Specific Patient

Select Study 20100464 - DOD - Nash
 Select a Patient

Select Form(s)

Form Name Anthropometric Data (Nash Study); Blood Testing (Select/Search Form
 Search Forms with fields Where Field ID Contains

Available Tables

Adverse Events; All Patient Labs; Demographics; More AE Details; More Pat Details; Pat Study Form Query; Pat Study Specimens; Patient Labs; Patient Orgs; Patient Protocols; Patient Schedule; Patient Specimens; Patient Study Stat; Treatment Arm

If one or more forms are selected, the data from Available Tables will be displayed only for those patients/studies that have data entered in the selected Forms(s).

Current User: Gregory Bigford
 System Timezone: (GMT-05:00) Eastern Time (US and Canada)

- The selected form(s) will auto-populate
- Click on the NEXT button:

Current Page: Ad-Hoc Query >> Field Selection

UHealth UNIVERSITY OF MIAMI HEALTH SYSTEM UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE

Study Search Patient Search Study Patients Report Central

Select Report Type >> Select Fields >> Filter Criteria >> Sort Criteria >> Preview & Save Next

Select Form/ Table Anthropometric Data (Nash Study)

☐ Select Field ID as 'Display Name' for all Fields
☐ Display Response Data Value in Report Output

Select	Field Name	Display Name	Field Id	Field Seq.
<input type="checkbox"/>	Study Number	Study Number	Study Number	10
<input checked="" type="checkbox"/>	Patient Id	Patient Id	Patient Id	20
<input type="checkbox"/>	Patient Study Id	Patient Study Id	Patient Study Id	30
<input type="checkbox"/>	Visit Name	Visit Name	Visit Name	40
<input type="checkbox"/>	Event Name	Event Name	Event Name	50
<input type="checkbox"/>	Protocol Name	Protocol Name	Protocol Name	60
<input type="checkbox"/>	Form Status	Form Status	Form Status	70
<input type="checkbox"/>	Response Id	Response Id	Response Id	80
<input type="checkbox"/>	Created By	Created By	Created By	90
<input type="checkbox"/>	Created On	Created On	Created On	100
<input type="checkbox"/>	Last Modified By	Last Modified By	Last Modified By	110
<input type="checkbox"/>	Last Modified On	Last Modified On	Last Modified On	120

Current User: Gregory Bigford
 System Timezone: (GMT-05:00) Eastern Time (US and Canada)

- Here you can select the specific fields you want displayed from the various forms that were selected
- Click on the NEXT button:

Current Page: Ad-Hoc Query >> Filter Definition

UHealth UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE

Study Search Patient Search Study Patients Report Central

Home Page Personalize Account Manage Protocols Library Manage Patients Budget Milestones Report Central Dashboards Ad-Hoc Queries Help Logout

Select Report Type >> Select Fields >> Filter Criteria >> Sort Criteria >> Preview & Save

New Specify Filter Name Add 0 more rows Refresh

Date Filter - Display data entered for:

All patient from status date of Select an Option to Select an Option

Year 2011 Month 8 2011 Date Range: From To

Exclude	Start Bracket	Select Field	Criteria	Value	End Bracket	And/Or
<input type="checkbox"/>	<input type="checkbox"/>	Select an Option	Select an Option		<input type="checkbox"/>	And
<input type="checkbox"/>	<input type="checkbox"/>	Select an Option	Select an Option		<input type="checkbox"/>	And
<input type="checkbox"/>	<input type="checkbox"/>	Select an Option	Select an Option		<input type="checkbox"/>	And
<input type="checkbox"/>	<input type="checkbox"/>	Select an Option	Select an Option		<input type="checkbox"/>	And
<input type="checkbox"/>	<input type="checkbox"/>	Select an Option	Select an Option		<input type="checkbox"/>	And
<input type="checkbox"/>	<input type="checkbox"/>	Select an Option	Select an Option		<input type="checkbox"/>	And
<input type="checkbox"/>	<input type="checkbox"/>	Select an Option	Select an Option		<input type="checkbox"/>	And
<input type="checkbox"/>	<input type="checkbox"/>	Select an Option	Select an Option		<input type="checkbox"/>	And
<input type="checkbox"/>	<input type="checkbox"/>	Select an Option	Select an Option		<input type="checkbox"/>	And
<input type="checkbox"/>	<input type="checkbox"/>	Select an Option	Select an Option		<input type="checkbox"/>	And

Current User: Gregory Bigford
System Timezone: (GMT-05:00) Eastern Time (US and Canada)

- Here you will have the option to filter the fields chosen by particular events/dates/parameters
- Click on the NEXT button:

Current Page: > Ad-Hoc Query >> Sort

UHealth UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE

Study Search Patient Search Study Patients Report Central

Home Page Personalize Account Manage Protocols Library Manage Patients Budget Milestones Report Central Dashboards Ad-Hoc Queries Help Logout

Select Report Type >> Select Fields >> Filter Criteria >> Sort Criteria >> Preview & Save

Select a Form or Table to specify Sort Criteria: Anthropometric Data (Nash Study)

Select Field	Sort Order
Select an Option	Select an Option
Select an Option	Select an Option
Select an Option	Select an Option

- Here you will have the option to sort how the fields are displayed in the report by particular event/dates/parameters
- Click on the NEXT button:

Current Page: Ad-Hoc Query >> Preview and Save

UHealth UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE

Study Search Patient Search Study Patients Report Central

Home Page Personalize Account Manage Protocols Library Manage Patients Budget Milestones Report Central Dashboards Ad-Hoc Queries Help Logout

Select Report Type >> Select Fields >> Filter Criteria >> Sort Criteria >> Preview & Save

Report Header

Report Footer

Save Report As *

Report Description

Shared With Private All Account Users All Users In a Group All Users in Study Team All Users in an Organization

Select Group Select Study Select Organization View List View List View List

e-Signature Submit

Note: Field sequence changes are applicable only after saving the report and is not applied to fields in 'Repeating Sections'

Display

- Here you can add details and descriptions that you want to appear in the report of the data (yellow box)
- At this point, your electronic signature will be required to save and display the report
- Select the DISPLAY button
- Below is an example of a report

Study Number	Patient Id	Visit Name	Protocol Name	Form Status	Created By	Created On	Last Modified By	Last Modified On	Form Version Number	Data Entry Date	Body Mass (kg)	Lean Mass (%)	Fat Mass (%)	Visit
Study - DOD- Nash	207464	Visit 1 (1 Month)	Calendar (Exercise, Diet, Lifestyle)	Completed	Eric Ponce	8/17/11 11:31			2	8/17/11	45			Visit 1
Study - DOD- Nash	207464	Wash In (-3 Month)	Calendar (Exercise, Diet, Lifestyle)	Completed	Richard Morris	7/28/11 10:31			2	8/16/11	129			Visit 4
Study - DOD- Nash	207464	Wash In (-3 Month)	Calendar (Exercise, Diet, Lifestyle)	Completed	Richard Morris	7/28/11 10:29			2	8/9/11	144			Visit 3
Study - DOD- Nash	207464	Wash In (-3 Month)	Calendar (Exercise, Diet, Lifestyle)	Completed	Richard Morris	7/28/11 10:31			2	8/23/11	137			Visit 5
Study - DOD- Nash	207464	Wash In (-3 Month)	Calendar (Exercise, Diet, Lifestyle)	Completed	Richard Morris	7/28/11 10:28			2	8/2/11	134	19	81	Visit 2
Study - DOD- Nash	207464	Wash In (-3 Month)	Calendar (Exercise, Diet, Lifestyle)	Completed	Richard Morris	7/28/11 10:27			2	7/26/11	142			Visit 1
Study - DOD- Nash	207508	Visit 2 (2 Month)	Calendar (Exercise Arm)	Completed	Eric Ponce	8/17/11 11:28			2	8/17/11	45	70	30	Visit 2
Study - DOD- Nash	207508	Visit 5 (5 Months)	Calendar (Exercise Arm)	Completed	Eric Ponce	8/17/11 11:30			2	8/17/11	60			Visit 5
Study - DOD- Nash	207508	Wash In (-3 Month)	Calendar (Exercise Arm)	Completed	Richard Morris	7/28/11 10:08			2	8/23/11	141			Visit 5
Study - DOD- Nash	207508	Wash In (-3 Month)	Calendar (Exercise Arm)	Completed	Richard Morris	7/28/11 10:07			2	8/2/11	145	18	82	Visit 2
Study - DOD- Nash	207508	Wash In (-3 Month)	Calendar (Exercise Arm)	Completed	Richard Morris	7/28/11 9:59	Richard Morris	7/28/11 10:06	2	7/26/11	139			Visit 1
Study - DOD- Nash	207508		Work In Progress	Richard Morris	7/12/11 11:46				2	7/12/11	144			Visit 1
Study - DOD- Nash	207508	Wash In (-3 Month)	Calendar (Exercise Arm)	Completed	Richard Morris	7/28/11 10:03	Richard Morris	7/28/11 10:05	2	8/9/11	146			Visit 3
Study - DOD- Nash	207508	Visit 4 (4 Months)	Calendar (Exercise Arm)	Completed	Eric Ponce	8/17/11 11:29			2	8/17/11	50			Visit 4
Study - DOD- Nash	207508	Wash In (-3 Month)	Calendar (Exercise Arm)	Completed	Richard Morris	7/26/11 10:40	Richard Morris	7/28/11 10:02	2	8/16/11	143			Visit 4
Study - DOD- Nash	207517	Wash In (-3 Month)	Calendar (Exercise, Diet, Lifestyle)	Completed	Richard Morris	7/28/11 10:48			2	7/19/11	154	19	81	Visit 2
Study - DOD- Nash	207517	Wash In (-3 Month)	Calendar (Exercise, Diet, Lifestyle)	Completed	Richard Morris	7/28/11 10:50			2	8/16/11	152			Visit 5
Study - DOD- Nash	207517	Wash In (-3 Month)	Calendar (Exercise, Diet, Lifestyle)	Completed	Richard Morris	7/28/11 10:48			2	7/12/11	156			Visit 1
Study - DOD- Nash	207517	Wash In (-3 Month)	Calendar (Exercise, Diet, Lifestyle)	Completed	Richard Morris	7/28/11 10:49			2	8/2/11	159			Visit 4
Study - DOD- Nash	207517	Wash In (-3 Month)	Calendar (Exercise, Diet, Lifestyle)	Completed	Richard Morris	7/28/11 10:49			2	7/26/11	154			Visit 3
Study - DOD- Nash	207617	Wash In (-3 Month)	Calendar (Exercise, Diet, Lifestyle)	Completed	Richard Morris	7/28/11 11:03			2	7/19/11	95	10	90	Visit 2
Study - DOD- Nash	207617	Wash In (-3 Month)	Calendar (Exercise, Diet, Lifestyle)	Completed	Richard Morris	7/28/11 11:02			2	7/12/11	96			Visit 1
Study - DOD- Nash	207617	Wash In (-3 Month)	Calendar (Exercise, Diet, Lifestyle)	Completed	Richard Morris	7/28/11 11:06			2	8/9/11	95			Visit 5
Study - DOD- Nash	207617	Wash In (-3 Month)	Calendar (Exercise, Diet, Lifestyle)	Completed	Richard Morris	7/28/11 11:03			2	7/26/11	91			Visit 3
Study - DOD- Nash	207617	Wash In (-3 Month)	Calendar (Exercise, Diet, Lifestyle)	Completed	Richard Morris	7/28/11 11:06			2	8/2/11	89			Visit 4

- Options are available for reports to be exported to WORD, EXCEL, OR STATISTICAL SOFTWARE programs for further analysis.

Form Abbreviations/Codes:

Screening Report	
Exclusion Criteria:	
Field Name:	Field ID (short form):
Structured exercise conditioning within 6 months of study entry?	s.SE
Defined diet involving caloric restriction or nutrient modification?	s.SD
Weight loss/gain of 5% within 6 months of study entry?	s.WLG
Surgery within 6 months of study entry?	s.SURG
Pressure ulcer within 3 months of study entry?	s.PUI
Upper limb pain that limits exercise?	s.ULP
Recurrent acute infection/illness requiring hospitalization of IV antibiotics?	s.II
Pregnant?	s.PRG
Previous MI or cardiac surgery?	s.MI
6 month history of glucose-lowering and/or lipid-lowering drug therapy?	s.GLT
Type I OR Type II diabetes?	s.DBT
Daily intake of vitamin supplementation exceeding 100% RDA?	s.VIT
Contraindicated disorder/condition (Traumatic brain injury)?	s.CD_TBI
Contraindicated disorder/condition (Substance abuse/dependence)?	s.CD_SA
Contraindicated disorder/condition (Psychiatric condition)?	s.CD_PC
Contraindicated drug therapy (β -adrenergic antagonists)?	s.CDT_B
Contraindicated drug therapy (Maintenance α -blockers)?	s.CDT_A
Contraindicated drug therapy (Methyldopa)?	s.CDT_M
Contraindicated drug therapy (Thiazide and loop diuretics)?	s.CDT_T
Contraindicated drug therapy (Parasympatholytics)?	s.CDT_P
Contraindicated drug therapy (Zinc)?	s.CDT_Z
Contraindicated drug therapy (Estrogen/hormone replacement therapy)?	s.CDT_E
Contraindicated drug therapy (Insulin-sensitizing drugs)?	s.CDT_I
Contraindicated drug therapy (Lipid-altering agents)?	s.CDT_L
Fasting Blood Glucose?	s.FBG
Fasting Blood Glucose (mg/dL)	s.FBG_VAL
Symptoms of Hyperglycemia?	s.H_G
Casual Plasma Glucose (mg/dL)	s.CPG
Plasma Glucose during OGTT?	s.PG_OGTT
Plasma Glucose after OGTT (mg/dL)	s.PG_OGTT_VAL
Inclusion Criteria:	
Field Name:	Field ID (Short form):
AISA (Injury Level)	s.IL
Injury Duration Greater than a year?	s.ID
Age between 18 - 65 yrs old?	s.AGE
Body Mass Index?	s.BMI
Body Mass Index (Kg/Msq)	s.BMI_VAL
Fasting Dislipidemia (HDL)?	s.FDL_HDL
Fasting Dislipidemia HDL (mg/dL)	s.FDL_HDL_VAL
Fasting Dislipidemia (Triglyceride)?	s.FDL_TG
Fasting Dislipidemia -Triglyceride (mg/dL)	s.FDL_TG_VAL
Impaired Fasting Glucose?	s.IFG
Impaired Fasting Glucose (mg/dL)	s.IFG_VAL
Patient Data	
Field Name:	Field ID (Short form):

Data Entry Date	s.DATE
Patient Code	s.ID
Height (Meters)	s.H
Body Mass (kg)	s.BM
Gender	s.G
Veteran	s.V

Anthropometric Report	
Field Name:	Field ID (Short form):
Data Entry Date	a.DATE
Visit	a.V
Body Mass (kg)	a.BM
Body Composition:	
Lean Mass (%)	a.LM
Fat Mass (%)	a.FM

Blood Testing Report	
Field Name:	Field ID (Short form):
Data Entry Date	b.DATE
Total Cholesterol (mg/dL)	b.TC
High Density Lipoprotein (mg/dL)	b.HDL
Low Density Lipoprotein (mg/dL)	b.LDL
Triglycerides (mg/dL)	b.TG
TG Response Curve	b.TGR
Insulin Resistance	b.IR
Ratios:	
Global CVD risk (TC:HDL)	b.TC_HDL
Global CVD risk (LDL:HDL)	b.LDL_HDL

Fitness Attributes Report	
Field Name:	Field ID (Short form):
Data Entry Date	f.DATE
Volume of Oxygen Consumption (VO2 - L/min)	f.VO2
Total Energy Expenditure (TEE - kCal/min)	f.TEE
Carbohydrate Oxidation (CHO - g/min)	f.CHO
Fat Oxidation (FO - g/min)	f.FO
Power Peak (W)	f.PP
Power Mean (W)	f.PM
1 repetition Maximum:	
Military Press (kg)	f.1RM_MP
Horizontal Rows (kg)	f.1RM_HR
Pec dec (kg)	f.1RM_PD
Preacher Curls (kg)	f.1RM_PC
Latissimus Pull-Downs (kg)	f.1RM_LP
Seated Dips ↑Rickshaw↓ (kg)	f.1RM_SD

Fitness Attributes Report	
Field Name:	Field ID (Short form):
Data Entry Date	f.DATE
Volume of Oxygen Consumption (VO2 - L/min)	f.VO2
Total Energy Expenditure (TEE - kCal/min)	f.TEE
Carbohydrate Oxidation (CHO - g/min)	f.CHO
Fat Oxidation (FO - g/min)	f.FO
Power Peak (W)	f.PP
Power Mean (W)	f.PM
1 repetition Maximum:	
Military Press (kg)	f.1RM_MP
Horizontal Rows (kg)	f.1RM_HR
Pec dec (kg)	f.1RM_PD
Preacher Curls (kg)	f.1RM_PC
Latissimus Pull-Downs (kg)	f.1RM_LP
Seated Dips ↑Rickshaw↓ (kg)	f.1RM_SD

DATA SAFETY MANAGEMENT BOARD (DSMB)

- The proposed trial is a multi-center study and participants may be at risk of injury.
- In accordance with institutional IRB (HRPO) directives we have empanelled a DSMB comprised of three (3) experts with distinguished medical and scientific credentials.

Sunil Sabharwal, M.D. is Chief of the SCI at the VA Boston Health Care System and Network SCI Service Line Director for VISN 1. He is an Assistant Professor of Physical Medicine and Rehabilitation at Harvard Medical School. Dr. Sabharwal has extensive clinical and research experience and expertise in SCI and its related medical complications. He serves on the SCI Committee of the American Board of Physical Medicine and Rehabilitation. He is Program Director for the SCI Fellowship at Harvard Medical School, and the National Hub-Site Director of the VA Fellowship in Advanced SCI Medicine. He is an active researcher in areas related to SCI and has co-authored manuscripts and book chapters in this field. Dr. Sabharwal is the recipient of several awards including the Outstanding Performance Award by the American Board of Physical Medicine and Rehabilitation and The Excellence Award by the American Paraplegia Society.

Jonathan Myers, Ph.D. is a VA Research Career Scientist, Rehabilitation Research & Development Service, VA Palo Alto Health Care System, Clinical Professor of Medicine at Stanford University, and a consultant to the Stanford Sports Medicine Program. He is a Fellow of the American College of Sports Medicine, American College of Cardiology, American Association of Cardiovascular and Pulmonary Rehabilitation, and the American Heart Association. Dr. Myers graduated from the University of California, Santa Barbara, and performed graduate studies at San Diego State University and the University of Southern California. He has been performing research, teaching, and writing in regard to exercise testing and training for over 20 years. His research interests include cardiopulmonary exercise testing, exercise training in chronic heart failure, epidemiology related to exercise test response and physical activity patterns, and cardiovascular health in spinal cord injury. **His clinical, research, and teaching activities at Stanford and the VA include statistical and databasemanagement, which allow him to oversee research methods and hypothesis testing for the DSMB.**

Dr. Myers has published more than 300 articles on exercise physiology, exercise testing, and exercise training, and has co-authored with Dr. Victor Froelicher a leading textbook on, "Exercise and the Heart, Clinical Concepts". He has authored or co-authored guidelines on exercise testing and related topics for numerous organizations, including the AHA, American Thoracic Society, ACSM, and the European Working Group on Exercise Physiology and Rehabilitation. Presently, he manages day-to-day research activities in the Cardiology Department at the Palo Alto Veterans Affairs Medical Center, and is coordinator for the Cardiology Exercise Laboratory.

Randall E. Keyser, Ph.D. is Associate Professor in the Department of Global and Community Health at George Mason University, Washington DC. Dr. Keyser received his Ph.D. in exercise physiology and experimental medicine from the University of Toledo and post-doctoral experience in cardiovascular disease at Harper Hospital, Wayne State University School of Medicine. He subsequently served as Chief of Cardiovascular Physiology and Rehabilitation at Butterworth Hospital where he investigated the influence of active muscle mass on cardiac regulation during maximum and sub-maximal exercise in patients with cardiovascular disease. He held faculty research and teaching positions at both Michigan State and Grand Valley State Universities at that time. Dr. Keyser then led the development and implementation of the Ph.D. in Physical Rehabilitation Science Program at the University of Maryland School of Medicine, where he served as its Director. He also served as the Department of Physical Therapy and Rehabilitation Science, Director of Research and as the Director of the Medical School's Exercise and Applied Physiology Core Laboratory in its NIH funded General Clinical Research Center. Dr. Keyser is currently the Lead Associate Investigator and site Principal Investigator on a project funded intramurally by the NIH and in collaboration with INOVA Healthcare investigating mechanisms of impairment and exercise induced improvement in patients who have pulmonary hypertension. Dr. Keyser is a Fellow of the American College of Sports Medicine, an Associate Editor for *Medicine and Science and Sports and Exercise*, and a Clinical Scientist in the Department of Rehabilitation Medicine and at the National Institutes of Health, Clinical Center.

The DSMB will:

- a. Review all unanticipated problems involving risk to volunteers or others, serious adverse events, and all volunteer deaths associated with the protocol, and provide an unbiased written report of the event within 10 calendar days.
- b. Comment on the outcomes of the adverse event and relationship of the event to the protocol or test article.
- c. Indicate whether they concur with the details of the report provided by the PI on such protocols, events, or test articles.
- d. Generate reports for prompt forwarding to the HRPO for events determined by either the PI or the DSMB to be possibly or positively related to participation, or resulting in death.

In surpassing DOD mandates for study monitoring the DSMB will:

- a. Assure that the study is being conducted according to high scientific and ethical standards.
- b. Assess study performance for recruitment, retention and follow-up, protocol adherence, and data quality and completeness; all to assist in successful and timely study completion.
- c. Review, consider, and approve (if proposed) protocol modifications.
- d. Advise the sponsor and the study investigators on necessary modification of study practices and procedures.
- e. Review study data, analyses, and findings in advance of publication or presentation.

DSMB meeting format:

The DSMB will formulate operating procedures in its first meeting, including types and formats of reports it will expect from the PI, and how its outputs will influence study policies and procedures. It will elect its own chair, and meet semi-annually to monitor cumulative safety data.

Communication of DSMB recommendations:

Should the DSMB determine that the study:

- a. Has answered the primary study question
- b. Is futile or will not reach a firm conclusion
- c. Is not being conducted according to high scientific or ethical standards OR
- d. Poses an unreasonable or unnecessary risk to study participants

It can recommend to the sponsor that the study protocol be terminated, temporarily suspended, or amended, as appropriate. DSMB reports will be included in the IRB-mandated continuing and final reports for all participating centers.

SUBJECT INFORMATION AND INCLUSION/EXCLUSION CRITERIA

Name:	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>
Code:	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>
D.O.B.	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>
Height:	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>
Weight:	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>

INCLUSION CRITERIA:			
Injury level	AIS A-C C5-L1	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>
Injury duration	> 1 year	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>
Age	18-65 years	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>
Gender	Male 80% Female 20%		<input type="checkbox"/>
Racial/Ethnic background	All		<input type="checkbox"/>
Population	Military and civilian constituents		<input type="checkbox"/>
BMI	≥ 20 kg/m ²	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>
Fasting dyslipidemia	HDL-C ≥ 40 mg/dL OR TG ≤ 150 mg/dL	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>
Impaired fasting glucose	≥ 100 mg/dL	<input style="width: 95%;" type="text"/>	<input type="checkbox"/>

EXCLUSION CRITERIA:	
Structured exercise conditioning within 6 months of study entry	<input type="checkbox"/>
Defined diet involving caloric restriction or nutrient modification	<input type="checkbox"/>
Weight loss/gain of 5% within 6 months of study entry	<input type="checkbox"/>
Surgery within 6 months of study entry	<input type="checkbox"/>
Pressure ulcer within 3 months of study entry	<input type="checkbox"/>
Upper limb pain that limits exercise	<input type="checkbox"/>
Recurrent acute infection/illness requiring hospitalization of IV antibiotics	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Previous MI or cardiac surgery	<input type="checkbox"/>

6 month history of glucose-lowering and/or lipid-lowering drug therapy	<input type="checkbox"/>		
Type I OR Type II diabetes	<input type="checkbox"/>		
Daily intake of vitamin supplementation exceeding 100% RDA	<input type="checkbox"/>		
Contraindicated disorder/condition:	<input type="checkbox"/>		
<ul style="list-style-type: none"> ▪ Traumatic brain injury ▪ Substance abuse/dependence ▪ Psychiatric condition 			
Contraindicated drug therapy:	<input type="checkbox"/>		
<table border="0" style="width: 100%;"> <tr> <td style="vertical-align: top; width: 50%;"> <ul style="list-style-type: none"> ▪ β-adrenergic antagonists ▪ Maintenance α-blockers ▪ Methyl dopa ▪ Thiazide and loop diuretics </td> <td style="vertical-align: top; width: 50%;"> <ul style="list-style-type: none"> ▪ Zinc ▪ Estrogen/hormone replacement therapy (excluding oral contraceptives) ▪ Insulin-sensitizing drugs ▪ Lipid-altering agents </td> </tr> </table>	<ul style="list-style-type: none"> ▪ β-adrenergic antagonists ▪ Maintenance α-blockers ▪ Methyl dopa ▪ Thiazide and loop diuretics 	<ul style="list-style-type: none"> ▪ Zinc ▪ Estrogen/hormone replacement therapy (excluding oral contraceptives) ▪ Insulin-sensitizing drugs ▪ Lipid-altering agents 	
<ul style="list-style-type: none"> ▪ β-adrenergic antagonists ▪ Maintenance α-blockers ▪ Methyl dopa ▪ Thiazide and loop diuretics 	<ul style="list-style-type: none"> ▪ Zinc ▪ Estrogen/hormone replacement therapy (excluding oral contraceptives) ▪ Insulin-sensitizing drugs ▪ Lipid-altering agents 		

Fasting blood glucose ≥ 126 mg/dL after a fast of 8+ hours	<input type="text"/>	<input type="checkbox"/>
OR		
Symptoms of hyperglycemia and casual plasma glucose ≥ 200 mg/dL	<input type="text"/>	
OR		
2-hour plasma glucose \geq during an OGTT using a glucose load of 75g	<input type="text"/>	

FOOD INTAKE LOG – THE MEDITERRANEAN-STYLE DIET

BREAKFAST		
Food Group	Food Item	Amount/Serving
Fruit		
Vegetable		
Dairy (low fat)		
Protein-rich food		
Whole grain		
Oil		

LUNCH		
Food Group	Food Item	Amount/Serving
Fruit		
Vegetable		
Dairy (low fat)		
Protein-rich food		
Whole grain		
Oil		

DINNER		
Food Group	Food Item	Amount/Serving
Fruit		
Vegetable		
Dairy (low fat)		
Protein-rich food		
Whole grain		
Oil		

SNACK		
Food Group	Food Item	Amount/Serving
Fruit		
Vegetable		
Dairy (low fat)		
Protein-rich food		
Whole grain		
Oil		

<u>EXTENTION PHASE - MONTHLY INTERVENTION.</u>	
Topic	
Data Collection	<input type="checkbox"/>
Review of self-monitoring records	<input type="checkbox"/>
Review of homework	<input type="checkbox"/>
Introduction of new topics*	<input type="checkbox"/>
Completion of action plan	<input type="checkbox"/>
Scheduling of next meeting	<input type="checkbox"/>

*only on bi-monthly *face-to-face* meeting with life-style coach.

LIFESTYLE BALANCE MANUAL



OBESITY/OVERWEIGHT IN PERSONS WITH EARLY AND CHRONIC SCI: A RANDOMIZED MULTI-CENTER CONTROLLED LIFESTYLE INTERVENTION

LIFESTYLE BALANCE MANUAL

PERSONAL NOTEBOOK



NAME:		
MY LIFESTYLE COACH IS:		
	ADDRESS:	
	PHONE:	

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PERSONAL DATA AND SCREENING ASSESSMENT

Code:	
D.O.B.	
Height:	
Weight:	

Injury level		AIS A-C C5-L1
Injury duration		> 1 year
Age		18-65
Gender		
Racial/Ethnic background		
Population		
BMI		≥ 20 kg/m ²
Fasting dyslipidemia		HDL-C ≥ 40 mg/dL OR TG ≤ 150 mg/dL
Impaired fasting glucose		≥ 100 mg/dL

OVERVIEW

Body weight gain through addition of fat is commonplace after SCI, and is likely caused by physical deconditioning, loss of metabolically active muscle mass, reduced whole body energy expenditure, restricted choices for exercise conditioning, and a diet that is too high in calories and fat. Health risks posed by obesity are strongly associated with 15 conditions including: cardiometabolic syndrome, hypertension, diabetes, coronary artery disease, congestive heart failure, stroke, osteoarthritis, sleep apnea, depression, cancer, respiratory failure, disorders of coagulation, and degenerative joint disease. Irrespective of cause, weight gain following SCI brings about diminished work capacity, musculoskeletal decline, pain, accelerated cardiovascular disease (CVD), worsening of neurological status, and progressive life dissatisfaction. It is also disturbingly co-morbid with dyslipidemia, glucose intolerance, and insulin resistance, has wide-ranging effects on health and function, and is far more difficult to manage and reverse than obesity occurring in persons without disability.

TO ADDRESS THIS PROBLEM YOU ARE BEING ASKED TO PARTICIPATE IN A RESEARCH STUDY because you have a spinal cord injury resulting in paraplegia or tetraplegia, have been injured for more than one year, and are 18-65 years old. The purpose of this study is to determine whether exercise alone, or the combination of exercise and diet with professional support, will reduce body weight and decrease your risk for developing obesity, and related cardiovascular disease and diabetes. This study will use methods from the National Institutes of Health Diabetes Prevention Program (DPP) trial, and modify the exercise programs to fit the needs and abilities of people with spinal cord injuries. The study methods will then examine whether this eighteen-month program (one year and a half) involving supervised and unsupervised treatment can lower your body weight, reduce your body fat, reduce your risk factors for developing heart disease and diabetes, and improve your quality of life. The U.S. Department of Defense is the sponsor of this study and is providing the funding for this study.

STUDY PARTICIPANTS:

You are one of eighty (80) individuals with spinal cord injury (SCI) who are expected to participate in this study. Sixty-four are expected to be men and 16 women.

You have qualified for this study because you have met ALL of the following screening characteristics:

- you have an SCI between C5 and L1 (the neck and the lower spine)
- you have been injured more than one year
- you are 18-65 years old
- you use a wheelchair as your primary means of mobility
- the relationship between your height and weight indicates you are overweight
- One or more of your fasting blood fat levels, and your fasting blood sugar, are outside of acceptable ranges

You are disqualified from participating, or may be disqualified, if ANY of the following are true or become true:

- you had a head injury along with your SCI
- you experience repeated infections that require antibiotics or hospitalization
- you have lost or gained 5% of your body weight within the past 6 months

- you have had surgery with the last 6 months
- you have had a pressure ulcer within the last 3 months
- you have arm, shoulder, or upper back pain that limits your ability to exercise
- you are currently taking antibiotics
- you have diabetes
- you have taken medications for diabetes, high blood pressure, or cholesterol within the past 6 months
- You are taking any of the medications that we will discuss with you, including high doses of vitamins and minerals
- You are unable or unwilling to eat the test meal for any reason. The test meal is explained in greater detail below and contains cooked eggs and cooked red meat
- You have undergone a structured exercise conditioning program for leisure or competition within the past 6 months

DURATION OF STUDY:

You will be enrolled in this study for approximately 21 months. During the initial 3 months you will be instructed to maintain your typical eating and activity habits. At the beginning of the 4th month you will be randomized (as by the flip of a coin) to one of two study groups. One study group (1) will undergo exercise, a test diet, and an educational program taught by the study investigators. The other study group (2) will undergo the same exercise program but maintain their usual diet. The study participants in this group will meet with the study investigators for the same amount of time as persons randomized to group 1, but not receive the same educational program. After 5 months of treatment you will work with a study coordinator to identify a type of exercise you would find appealing when continued in the home setting. Choices include resistance exercise (weight lifting) with elastic bands, boxing, or other exercise you can perform at home. You will then perform the selected exercise in the laboratory for your last month of supervised exercise, which will allow the Investigators to monitor your progress and make any suggestions for use of the equipment. At the end of the 6th study month you will continue the exercise at home for another 12 months.

The following table shows what the Investigators will be studying, and when. Each study activity and the time needed to accomplish it will be described. Treatments for group 1 (Exercise, Diet, and Behavior) and 2 (Exercise Only) will begin at study month 0. Thus, you will be studied for 3 months before treatments begin (-3 months).

Study outcome	Outcome sampling time points (by month)									
	-3	0	1	2	3	4	5	6	12	18
Body mass	▪	▪	▪	▪	▪	▪	▪	▪	▪	▪
Body composition by DXA		▪						▪		▪
Insulin resistance	▪	▪			▪			▪	▪	▪
Caloric expenditure – intake	▪	▪						▪	▪	▪
Fitness	▪	▪						▪	▪	▪
• Endurance testing										
○ Total energy use										
○ Carbohydrate utilization										
○ Fat utilization										
• Strength testing										

• Power testing										
Cardiovascular disease risk	▪	▪			▪			▪	▪	▪
• TC:HDL										
• LDL:HDL										
• TG										
Post-prandial lipemia	▪	▪						▪		▪
• Δ TG response curve										
• Fat oxidation										
HRQoL	▪	▪			▪			▪	▪	▪

In addition to the described studies, we will quickly test your strength each month during months 1-6 using methods that are described below. We will test your strength in this way so that we can determine the resistance used during the exercise training sessions as you become stronger.

DESCRIPTION OF STUDY OUTCOME VARIABLE MEASUREMENTS

Body mass - To measure your body weight you will wheel your wheelchair on a scale where you and the wheelchair will be weighed. You will then transfer to a therapy mat and the chair will be weighed without you. The difference between the two measurements is your body weight.

Body composition - To measure the amount of muscle and fat your body contains you will undergo a scan. You will be assisted in a transfer to a machine, and will be asked to lie quietly while a series of low energy x-ray scans will be made from your head to toe. The scan will calculate how much muscle and fat is contained in various parts of your body. The whole body scan will require about 10 minutes.

Fitness tests - You will undergo three types of fitness tests for endurance, power, and strength.

- **Endurance and power testing** - An arm exercise test will examine whether there are reasons that you should not undergo the exercise testing (such as risks of heart damage or abnormal responses to exercise) and determine your level of fitness. You will be prepared with electrode patches placed on your chest and stomach, and have a soft flexible mask placed over your nose and mouth. The mask will collect air that you breath out during exercise and allow the Investigators to determine how hard you are working. After preparation and instructions are completed you will position your wheelchair in front of an arm exercise machine and begin exercising at a low level. Every three minutes the resistance on the machine will increase making it harder to exercise. You will be instructed to work as hard and long as possible, but can stop the test at any time. The Investigators will be monitoring the rhythm of your heart and breathing responses while you exercise, and may stop the test at any time if they feel you have completed the test or your continued exercise may pose a hazard. After testing the Investigators will monitor your heart rhythm for 10 minutes and provide water and a towel.

A separate arm exercise test will determine how much power you can create with your arms. After preparation and instructions are completed you will position your wheelchair in front of an arm exercise machine and begin exercising at a low level. After about a minute of warm up you will be instructed to pedal as fast as you can without any resistance. Within 3 seconds, your pedaling will be resisted by weights placed on the flywheel. You will continue to pedal as fast as you can for 30 seconds. After 30 seconds you will stop, the test will be over, and you will be provided water and a towel.

- **Strength testing** - To determine the resistance levels assigned for your exercise session the Investigators will measure your maximum strength on a weight-lifting machine adapted for use by persons in a wheelchair. Testing will be performed using six weight-lifting maneuvers: The initial test for each station will be set at light weight. You will be instructed to perform eight repetitions of each maneuver at this weight, with each repetition lasting six seconds (3 seconds lifting, 3 seconds lowering). If eight repetitions are completed in controlled fashion the weight will be increased and the exercise repeated. You will continue to lift until you cannot complete 8 repetitions in a controlled manner using good lifting form.

Dietary habits - After providing instructions on measuring and recording of foods you eat, we will give you an intake form to take home to write down what you eat for two days. After two days you will return the record for review, receive additional instructions if needed, and then write down what you eat for another two days, returning the notebook and materials to us at the end of the two days. The information you provide will be entered in a computer and analyzed for how many calories you eat and the nutrients in your food. If you are randomized to Group 1 you will be taught to change your diet. If you are randomized to group 2 you will keep eating like you always have.

Insulin resistance and risk of cardiovascular disease - To minimize the amount of blood we will take from you, the fasting blood sample for insulin, glucose (sugar), and lipids (fats, like cholesterol) will be measured on samples taken before you eat your meal. As there is no meal testing scheduled for months 3 and 12, we will instruct you to come to the Lois Pope Life Center in the fasted state and we'll take one sample of blood (15 ml = 3 teaspoons).

Response of blood fats and body metabolism to food intake - To test how your body digests a meal, you will arrive at the testing center on the first day of testing during the 8 – 10 day assessment period. You will restrict your intake of beverages containing alcohol and caffeine (such as cola and coffee) the day before fasting and fast overnight, but you will be allowed to drink water in the morning. To obtain blood samples a flexible plastic catheter (tube) will be placed in a vein near the surface of your forearm. A blood sample (3 teaspoons) will be drawn from the tube so that no additional needle sticks of your arm will be needed. A soft flexible mask will be placed over your nose and mouth. The mask will collect air that you breathe out while you sit still for 15 minutes. This allows the Investigators to determine how much energy your body uses while you are sitting still. Then, the mask will be removed and you will then be given a McDonald's breakfast meal consisting of an egg McMuffin, hash brown potatoes, and a small bottle of an orange soda that contains sugar. You will be allowed 15 minutes to consume the meal, after which the test will start. Blood samples (15 ml = 3 teaspoons each) will be taken at the start of the test, and at 30 minutes, 60 minutes (1 hour), 120 minutes (2 hours), 180 minutes (3 hours), and 240 minutes (4 hours) after eating the breakfast food. After the 240 minute (4 hour) sample you will be given a McDonald's lunch containing a Quarter Pounder with cheese, French fries, and a soda. Additional blood samples will then be taken at 300 minutes (5 hours), and 360 minutes (6 hours). In addition to the blood sampling, the soft flexible mask will again be placed over your nose and mouth at each of these time points (0, 30, 60, 120, 180, 240, 300, and 360 minutes) which will allow the Investigators to determine your metabolic responses to food intake. Between measurements you will be allowed to read, watch television, or nap, but will be asked to not exert yourself. You may not eat any other foods or snacks until the end of the test, but may drink plain water. You may bring any materials you wish to occupy yourself. At the conclusion of the test the catheter will be removed and pressure applied to stop any bleeding. The total amount of blood taken will be 24 teaspoons (120 ml), which is about one-quarter of a pint of blood. After your blood has been analyzed in the laboratory the leftover volumes will be destroyed.

Health related quality of life (HRQoL) - At six time-points of the study you will take four paper and pencil tests to see how you are feeling about life and your health. Some of the questions will ask you about your feelings about the relationship between your health and the quality of your life, some will ask you about how much support you need from those with which you come in contact and how you feel about that, and some will ask you if you have been sad, depressed and nervous.

PROCEDURES

Initial visit and assessment - If you are given clearance to participate by the study physician you will undergo a series of assessments. All of the assessments will be performed 3 months before you begin exercise training. Some assessments provide baseline data, and some are used for both assessment and data collection.

If it is found during the initial exercise test that the exercise may pose a risk to your heart you may be excused for the study. The same is true if the resistance exercise causes pain, or the test of your sugar shows that you have diabetes. If you have a mild form of diabetes you may still be enrolled in the study, although if it doesn't improve by the time of the 3 month study sampling, you may be released from the study and referred for needed medical treatment of the condition.

During the first 3 study months you will keep your diet and exercise activities unchanged. Once this part of the study is finished, all study participants will undergo exercise conditioning and those randomized to Group 1 will begin the diet and behavioral training sessions.

EXERCISE TRAINING SESSIONS:

1 hour/session – 3 x weekly – 24 weeks

Each of your exercise training sessions is to be performed in the clinic (initial 6 months) and will last 45-60 minutes and employ resistance training (weight lifting) and high-speed, low resistance activities (arm cranking). You will perform 10 repetitions of lifting. Every time you complete two resistance exercises you will perform arm exercise for two minutes on a stationary machine. You will rest 10 seconds between each set of repetitions, and will complete three cycles of the exercises. At the end of each month we will retest your strength and change the weight you lift to match your change in strength. Sessions will be on non-consecutive days within a week (Monday-Wednesday-Friday).

BEHAVIOR AND DIETARY TRAINING SESSIONS:

1 hour/session – Once weekly – 16 weeks

If you have been assigned to Group 1, you will participate in 16 educational sessions that will focus on behavioral control of your body weight. If you have someone who does your food shopping and cooking they are welcome to attend the sessions. The sessions will include information about ways to eat, changing your diet to one that is healthier, and what to do if you feel like overeating. The diet being used for Group 1 will include lean meats and fish, healthy fruit and vegetables, and products with olives and olive oil. For education sessions 7, 8, and 10 the two groups will receive different types of information.

The topics of the sessions are listed in the following table:

	CORE INTERVENTION TRAINING CURRICULUM.	
	Session	Topic
Focus is on diet and exercise goals and education	1	Introduction to lifestyle intervention. Explain study goals.
	2	Introduce self-monitoring of weight at home.
	3	Teach 3 ways to eat less fat.
	4	Educate about healthy eating. Recommend alternate foods.
	5	Introduce physical activity modules.
	6	Tailor physical activity regimen to needs of the individual.
	7	-Teach principles of energy balance between calories and exercise. -Teach principles of health maintenance from exercise.
	8	-Introduce principles of stimulus control as a method to prevent unhealthy eating. -Introduce principles of stimulus control as a method to maintain exercise adherence.
Focus is on psychosocial and behavioral strategies	9	Present five-step model of problem solving.
	10	Introduce basic skills for eating and exercising away from home. Introduce basic skills for exercising away from home.
	11	Practice identifying negative thoughts and how to counter them.
	12	Introduce concept that slips are part of lifestyle change and provide tips for behavioral change maintenance.
	13	Introduce principles of aerobic fitness and coping with boredom.
	14	Provide strategies for managing social cues, both stressful and supportive.
	15	Summarize stress management principles presented over the course of the intervention.
	16	Focus on enhancing motivation and maintaining behavioral change post-lifestyle intervention.

LIFESTYLE COACH:

At the beginning of the study you will be teamed with a Lifestyle Coach, who will help you to modify your behaviors and assume a healthier lifestyle. The Lifestyle Coach may attend some of your training sessions, and might contact you if you need assistance. You may also call this individual if you are in need of additional support.

As part of the study you will be contacted every 1-2 weeks to see how you are managing your exercise and diet. Contacts will be made through a Viterion system, which is an electronic box that links with your regular telephone cable. The software on the Viterion will ask you a series of questions, most of which can be answered as 'yes' or 'no'. You will simply answer these questions and the information will be transmitted to a team specialist. If you are not keeping up with your exercise or you need additional personal support, you will receive a call from your Lifestyle Coach, who will offer assistance and try to work through any study problems you may be experiencing.

SESSION OUTLINE FOR CORE INTERVENTION CURRICULUM

Session 1A:

Welcome to the Lifestyle Balance Program

Objectives:

In this session, you will:

- Meet the lifestyle coach and study team.
- Review the Standard Healthy Lifestyle Guidelines, if not presented at the time you receive your study group assignment.
- Be given the Lifestyle Balance notebook.
- Discuss your initial reaction to being assigned to the Lifestyle Balance group.
- Receive an overview of the Lifestyle Balance Program.
- Learn the two Lifestyle Balance goals and why they are important.
Discuss key aspects of the coach-participant relationship

Choose to focus either on the weight loss or the physical activity goal first.

Session 1B:

Getting Started Losing Weight

Objectives:

In this session, as you have chosen to focus on the weight loss goal first, you will:

- Learn the reason for self-monitoring foods eaten and the basic principles of self-monitoring.
- Be assigned self-monitoring of foods eaten and circling of high-fat foods; practice this.

You will receive weighing and measuring tools.

Session 2:

Be a Fat Detective

Objectives

In this session, you will:

- Begin to graph weight and be assigned self-monitoring of weight.
- Learn the reason for basic principles of self-monitoring fat grams.
- Receive your fat gram goal.
- Practice finding foods in the Fat Counter and figuring out the number of fat grams in foods.

Learn to calculate a running fat gram total for the day.

Session 3:
Three Ways to Eat Less Fat

Objectives:

In this session, you will:

- Review self-monitoring skills, and learn in more detail how to weigh and measure foods, by guessing the amounts of selected high-fat foods, actually measuring the amounts, and then calculating the fat grams.
- Learn three ways to eat less fat.
- Make a plan to eat less fat.

Session 4:
Healthy Eating

Objectives:

In this session, you will:

- Discuss how eating less fat fits into the overall context of healthy eating.
- Review the Food Guide Pyramid and its recommendations, including to lower fat.
- Compare your eating pattern to the Food Guide Pyramid.
- Review more examples of ways to eat lower-fat foods instead of high-fat foods.

Be introduced to the importance of eating more grains, vegetables, and fruits.

Session 5:
Move Those Muscles

Objectives:

In this session, you will:

- Receive the Lifestyle Balance activity goal.
- Discuss why the activity goal is important.
- Discuss current level of physical activity.
- Be encouraged to participate in the Lifestyle Balance activity sessions.
- Identify other activities equivalent to brisk walking that you enjoy.

You will develop an activity plan for the coming week that includes the Lifestyle Balance activity sessions and other moderate activities that you enjoy.

Session 6:
Being Active: A Way of Life

Objectives:

In this session, you will:

- Begin to graph activity.
- Discuss time as a barrier to activity.
- Learn two different ways to find the time to be active.
- Discuss lifestyle activity.
- Discuss ways to prevent injury and receive handouts on how to do some simple stretches and when to stop exercising.
- Develop an activity plan for the coming week (for most participants, this will be a weekly total of 90 minutes).

Session 7:
Tip the Calorie Balance

Objectives:

In this session, you will:

- Discuss how healthy eating and being active are related in terms of calorie balance.
- Discuss how calorie balance relates to weight loss.
- Review your progress so far in terms of a) changes made in fat/calorie intake and activity, and b) weight change. Discuss how this relates to calorie balance.
- Develop an activity plan for the coming week.

If weight loss is less than what is expected, you will make a plan for the coming week to either self-monitor calories or follow a low-calorie meal plan, or both.

Session 8:
Take Charge of What's Around You

Objectives:

In this session, you will:

- Learn about food and activity cues and ways to change them.
- Mentally search the participant's home, work place, and where the participant shops for food, looking for problem food cues and discussing ways to change them.
- Learn ways to add positive cues for activity and get rid of cues for inactivity.
- Develop an activity plan for the coming week (150 minutes per week).

Session 9: Problem Solving

Objectives:

In this session, you will:

- Learn the five steps to problem solving.
- Practice the steps using a problem you are experiencing now with eating less fat/calories or being more active.

Session 10: Four Keys to Healthy Eating Out

Objectives:

In this session, you will:

- Learn four basic principles for healthy eating out: **planning ahead, assertion, stimulus control, and healthy food choices.**
- Identify specific examples of how to apply these principles at the type of restaurant you go too often.
- Practice making a meal selection from an appropriate menu.
- Practice out loud how to ask for a menu substitution.

Session 11: Talk Back to Negative Thoughts

Objectives:

In this session, you will:

- Recognize that everyone has negative thoughts and identify examples of them.
- Learn how to stop negative thoughts and talk back to them with positive ones.
- Practice stopping negative thoughts and talking back to them with positive ones.

Session 12: The Slippery Slope of Lifestyle Change

Objectives:

In this session, you will:

- Review your progress since Session 7 or 8 (“Tip the Calorie Balance”).
- Identify some things that cause you to slip from healthy eating or being active.
- Discuss what to do after a slip to “get back on track again.”

Session 13:
Jump Start Your Activity Plan

Objectives:

In this session, you will:

- Discuss ways to add interest and variety to your activity plans.
- Learn the definition of “aerobic fitness.”
- Learn the F.I.T.T. Principles (frequency, intensity, time, and type of activity) as related to heart (aerobic) fitness.

Session 14:
Make Social Cues Work *for* You

Objectives:

In this session, you will:

- Review examples of problem social cues and helpful social cues.
- Discuss ways to change problem social cues and add helpful ones.
- Review strategies for coping with social events such as parties, vacations, visitors, and holidays.
- Make an action plan to change a problem social cue and add a helpful one.

Session 15:
You Can Manage Stress

Objectives:

In this session, you will:

- Discuss how to prevent stress and cope with unavoidable stress.
- Discuss how the intervention curriculum and objectives can be a source of stress and how to manage that stress.

Session 16:
Ways to Stay Motivated

Objectives:

In this session, you will:

- Receive a certificate of participation.
- Review your progress since Session 1, and if not at goal, develop a plan to attain your goal.
- Discuss the importance of motivation and ways to stay motivated.

RISKS AND DISCOMFORTS OF STUDY PARTICIPATION:

- The risks of blood drawing include: fainting, the occurrence of temporary discomfort and/or bruise at the site of puncture; rarely, infection or the formation of a small clot or swelling to the vein and surrounding area may occur. There may be slight discomfort in your arm or hand during the inserting of the catheter into the vein. Occasionally, a small accumulation of blood (hematoma) may form at the point of insertion of the catheter. This may result in a small lump that will disappear. Occasionally, a small amount of bleeding may occur around the catheter site. On rare occasions, a local infection may occur around the catheter site.
- You will be undergoing a series of assessments to test your strength, endurance, and power. You will also perform multiple weekly sessions of exercise including both strength and endurance exercises. During endurance testing and the exercise session you will wear a flexible mask over your nose and mouth to collect the air you exhale, which will allow the investigators to measure how hard you are working. The mask placed over the mouth and nose may feel confining, although the air flowing through it will not be restricted in any way.
- It is likely that you will feel tired after the exercise sessions. During intense arm cranking exercise you may injure your hands, arms, or shoulders, which may make your daily activities more difficult to perform.
- There is a risk of complications involving the heart. In exercise testing to exhaustion, 1 in 3000 persons sustains symptoms that require them to be seen by a physician or to be transported to a hospital. One in 30,000 persons sustains permanent heart damage or dies.
- After eating the morning meal you will not be served lunch. You may find yourself becoming hungry later in the day.
- The amount of radiation from the low energy x-ray scan of the whole body (DXA) is roughly equal to the amount of radiation experienced in one day's sunlight exposure, and so is not thought to be dangerous.
- In rare cases the tape used to affix the EKG electrodes to your chest can cause an allergic reaction. This normally goes away within several hours after they are removed.
- Completing the questionnaires may make you feel nervous or upset.

In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the research staff. You have the right to ask any questions about the potential and/or known hazards of this study at any time. You will be asked to tell the study doctor about any possible side effects you might have at any time during the study.

BENEFITS:

No direct benefit can be promised by taking part in this study. However, it is likely that you will become more fit from undergoing exercise conditioning. It is possible that the diet being tested may cause you to lose body weight.

ALTERNATIVES:

You have the alternative not to participate in this study. You can decide to stop participating in this study at any time. Not participating in this study will not affect your medical care. You can perform exercise and undergo diet without being part of this study.

COSTS:

You will not have to pay for the study procedures. However, you will be responsible for costs associated with your transportation to the medical center, and costs for parking if you need to park your vehicle.

INCENTIVES/PAYMENTS TO PARTICIPANTS:

You will be paid \$750 for your participation in the study. If you are a non-UM employee, you must complete a W-9 form in order to receive payment for participation. This information will not be linked to any of the study data and will only be used for payment purposes. You will receive \$250 of the payment after completing the supervised clinical program (6 months), another \$250 after completing half of the extension program (another 6 months), and the balance (\$250) after the study is completed (another 6 months). Payment will be made in the form of a check, which you should receive about 2-3 weeks after your paperwork is submitted for payment.

COMPENSATION FOR STUDY-RELATED INJURY:

You may be exposed to risk of injury from participation in this study. If injury occurs, treatment will in most cases be available. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not routinely available.

VOLUNTARY PARTICIPATION/WITHDRAWAL FROM THE STUDY:

Your participation in this study is voluntary. You may refuse to participate, or withdraw from the study at any time, without penalty or loss of benefits to which you are otherwise entitled. This will not affect the medical care you receive from the study doctor or UM/Jackson Memorial Hospital. You must tell the study doctor if you wish to stop taking part in the study. Your participation in this study may be discontinued, without your consent, at any time by the study doctor, if he/she believes that participation in the study is no longer in your best interest. The Institutional Review Board (IRB), regulatory authorities, or the sponsor may also discontinue your participation in the study.

You can contact the study doctor at:

Mark S. Nash, Ph.D., FACSM
Department of Neurological Surgery
University of Miami Miller School of Medicine
Lois Pope Life Center
1095 NW 14th Terrace, R-48
Miami, FL 33136
304 243-3628 (Office)
305 243-6946 (24 hour page operator)

If you cancel your permission after you have started in the study, the study staff and the study doctor will stop collecting your health information. Although they will stop collecting new information about you they may need to use the information they have already collected to evaluate the study results. If you start the study and then you cancel your permission, you will not be able to continue to participate in the study. This is because the study staff and/or the study doctor would not be able to collect the information needed to evaluate the study findings.

CONFIDENTIALITY:

By signing this consent, you authorize the Investigator(s) and his/her/their staff to access your medical records and associated information as may be necessary for purposes of this study. This information will also be shared with the Sponsor (U.S. Department of Defense) of this study, and persons working with the Sponsor to oversee the study.

Your records and results will not be identified as pertaining to you in any publication without your expressed permission.

The Investigators and their collaborators and staff will consider your records confidential to the extent permitted by law. The Food and Drug Administration (FDA), Department of Health and Human Services (DHHS), and U.S. Department of Defense may review these research records. Your records may also be reviewed for audit purposes by authorized University of Miami employees or other agents who will be bound by the same provisions of confidentiality.

Your paper records will be maintained in a locked file cabinet, placed within a locked office, which can only be accessed by a locked corridor at the Lois Pope Life Center. Electronic records will be stored on a computer at the Office of Research Information Management of the University of Miami, which is accessed by a password known to the Principal Investigator and his research staff, and to university computer maintenance personnel who are required to maintain the confidentiality of this information. The study site personnel may use your information to notify you of appointments, send you appointment reminders, or schedule additional appointments.

WHOM TO CONTACT:

If at any time you have any questions about the study, you may contact Mark S. Nash, Ph.D. at 305-243-3628.

In case of study-related injury, please contact Alberto Martinez-Arizala, M.D. at 305-368-0250 (24- hour pager).

If you have any questions relating to your rights as a research subject, please contact **the University of Miami's HUMAN SUBJECTS RESEARCH OFFICE (HSRO)**, at **305-243-3195**.

WEIGHT MIRROR

- As a component of the Behavioral Intervention, the Internet-based freeware, Weight Mirror, will be used to create a 'virtual image' of you which is 7% lighter than your actual weight at the onset of the study.
- Visualization of weight loss, in this manner, will be used as a motivational tool.
- A photograph will be taken of you at the onset of the study, and uploaded to the Weight Mirror program for virtual image creation.
- The original photograph will be used as a reference along with the virtual image.
- NEW photographs will be updated at 6, 12, and 18 months as a visual tool to monitor your progress.
- <http://makeovr.com/weightmirror/>

AGREEMENT OF DECISION TO PARTICIPATE

You will receive a copy of this signed informed consent form.

I have read this consent, which is printed in English (a language which I read and understand). This study has been explained to my satisfaction and all of my questions relating to the study procedures, risks and discomforts, and side effects have been answered. If I have any further questions regarding this study, or in the event of a study-related injury, I should contact the appropriate person named above. Based on this information, I voluntarily agree to take part in this study.

--	--

Signature of participant

Date

--

Printed name of participant

--	--

Signature of person obtaining consent

Date

--

Printed name of person obtaining consent

FOOD INTAKE LOG – THE MEDITERRANEAN-STYLE DIET

S	M	T	W	Th	F	Sat
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

BREAKFAST		
Food Group	Food Item	Amount/Serving
Fruit		
Vegetable		
Dairy (low fat)		
Protein-rich food		
Whole grain		
Oil		

LUNCH		
Food Group	Food Item	Amount/Serving
Fruit		
Vegetable		
Dairy (low fat)		
Protein-rich food		
Whole grain		
Oil		

DINNER		
Food Group	Food Item	Amount/Serving
Fruit		
Vegetable		
Dairy (low fat)		
Protein-rich food		
Whole grain		
Oil		

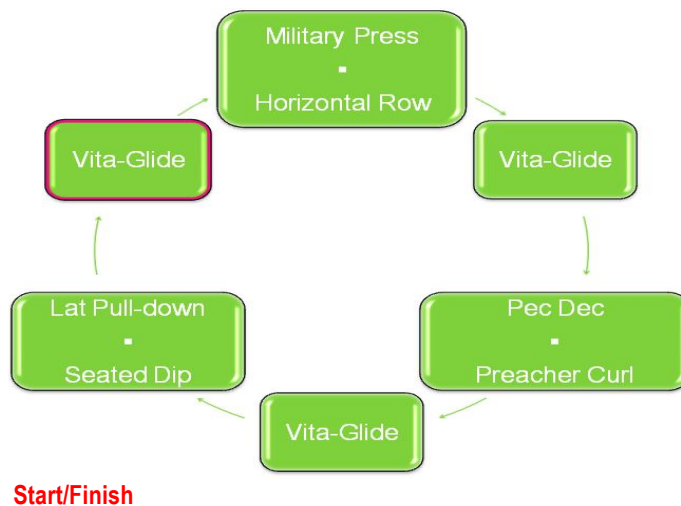
SNACK		
Food Group	Food Item	Amount/Serving
Fruit		
Vegetable		
Dairy (low fat)		
Protein-rich food		
Whole grain		

DESCRIPTION OF EXERCISE MANEUVERS UTILIZED IN CRT.

Exercise Maneuver	Description
Military Press	Shoulder abduction with scapular elevation and upward rotation starting from the fully adducted and depressed position.
Horizontal rows	Shoulder horizontal abduction with scapular adduction starting from a position of maximum forward reach.
Pec dec	Shoulder horizontal adduction while in external rotation to the midline, from the maximum tolerated horizontal abduction in external rotation.
Preacher curls	Elbow flexion supported on an inclined pad from the fully extended position.
Latissimus pull-downs	Shoulder adduction with scapular downward rotation and depression starting from the maximal upward reach position.
Seated dips ("Rickshaw")	Shoulder flexion, scapular depression, and elbow extension while maintaining arms as near the body as possible, from the fullest allowed point of shoulder joint extension, scapular elevation, and elbow flexion.

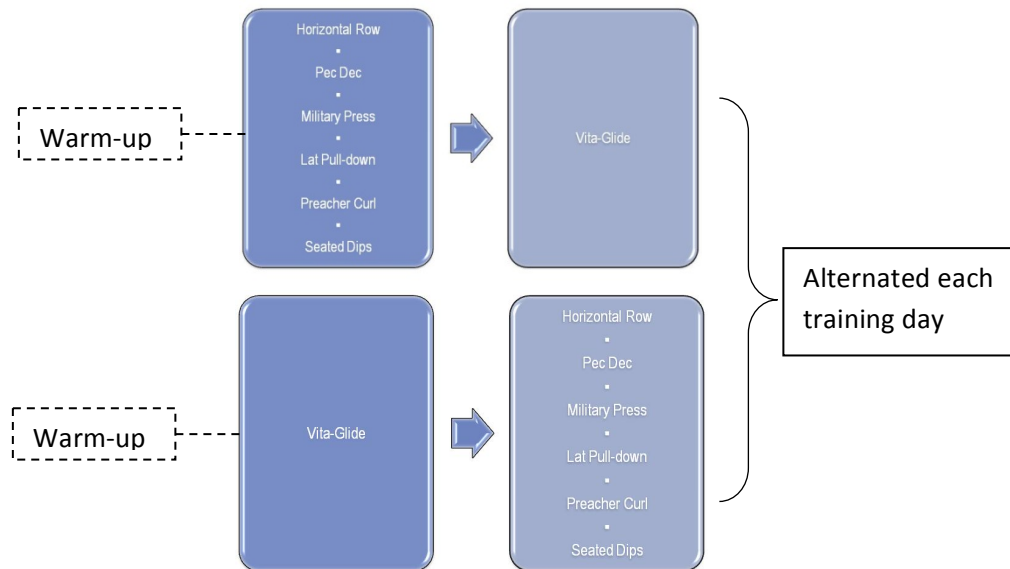
CRT training session design:

- Each training session will be preceded by a 2-minute warm-up on a Vita-glide® arm ergometer.
- Resistance exercises will be performed in pairs (2 maneuvers in succession) each incorporating 10 repetitions of each maneuver lasting six seconds (3 seconds concentric, 3 seconds eccentric).
- Two minutes of endurance exercise is then interposed using a Vita-glide® arm ergometer at a cadence of 50 rpm without applied resistance
- Two more resistance maneuvers are performed.
- These activities are alternated until the participant has rotated through each resistance station **three times**.



Modifications to CRT for participants with tetraplegia:

- Adaptations to work-out for persons with tetraplegia as high as the C5 level.
- Resistance maneuver order is altered to reduce time needed for changing the resistance stations.
- Resistance and endurance exercises are performed in contiguous time blocks – order of exercise (i.e. resistance and endurance) are alternated on each training day.
- Each training session will be preceded by a 10-minute warm-up on a Vita-glide® arm ergometer.
- Each resistance station will be performed **twice only**.



LIFESTYLE COACH MANUAL



OBESITY/OVERWEIGHT IN PERSONS WITH EARLY AND CHRONIC SCI: A RANDOMIZED MULTI-CENTER CONTROLLED LIFESTYLE INTERVENTION

BEHAVIORAL INTERVENTION- TIMELINE AND PROTOCOL

General Principles:

- 16-session protocol aimed at behavior modification through: education, stress management, problem solving skills training, and cognitive restructuring.
- Delivered by a **Lifestyle Coach** selected with consideration to gender, injury level, and military status.
- 16-session core curriculum training will be scheduled within the 24-week core intervention time frame.
- Individual sessions will be 30-60 minutes in duration.
- Following core curriculum training participants will be contacted monthly for the duration of the extension period.
 - *Face-to-face* contact with the life-style coach will occur bi-monthly.
 - *Off month* contact will be via the **TeleHealth** system.
- A **Lifestyle Manual** will be provided for each participant.

	CORE INTERVENTION TRAINING CURRICULUM.	
	Session	Topic
Focus is on diet and exercise goals and education	1	Introduction to lifestyle intervention. Explain study goals.
	2	Introduce self-monitoring of weight at home.
	3	Teach 3 ways to eat less fat.
	4	Educate about healthy eating. Recommend alternate foods.
	5	Introduce physical activity modules.
	6	Tailor physical activity regimen to needs of the individual.
	7	-Teach principles of energy balance between calories and exercise. -Teach principles of health maintenance from exercise.
	8	-Introduce principles of stimulus control as a method to prevent unhealthy eating. -Introduce principles of stimulus control as a method to maintain exercise adherence.
Focus is on psychosocial and behavioral strategies	9	Present five-step model of problem solving.
	10	Introduce basic skills for eating and exercising away from home. Introduce basic skills for exercising away from home.
	11	Practice identifying negative thoughts and how to counter them.
	12	Introduce concept that slips are part of lifestyle change and provide tips for behavioral change maintenance.
	13	Introduce principles of aerobic fitness and coping with boredom.
	14	Provide strategies for managing social cues, both stressful and supportive.
	15	Summarize stress management principles presented over the course of the intervention.
	16	Focus on enhancing motivation and maintaining behavioral change post-lifestyle intervention.

Session 1A: Welcome to the Lifestyle Balance Program

Objectives:

In this session, the participant will:

- Meet the lifestyle coach and study team.
- Review the Standard Healthy Lifestyle Guidelines, if not presented at randomization.
- Be given the Lifestyle Balance notebook.
- Discuss the participant's initial reaction to being assigned to the Lifestyle Balance group.
- Receive an overview of the Lifestyle Balance Program.
- Learn the two Lifestyle Balance goals and why they are important.
- Discuss key aspects of the coach-participant relationship and sign a related agreement.
- Choose to focus either on the weight loss or the physical activity goal first.

To Do Before the Session:

Get materials ready:

- Keeping Track book (or two, if the next session is scheduled more than 7 days later).
- Pages for participant notebook.
- Video or photographs of local study team members, if not present in person.
- Measuring cups, spoons, and scale (for participants who focus on weight loss first).
- Map to the supervised activity sessions (for participants who focus on activity first).

Invite family member to attend (if, during the run-in period, it was determined that a family member's attendance would enhance adherence).

On the Lifestyle Balance Update page, pencil in tentative appointment dates (schedule sessions 1-8 for one week apart, 9-16 for either one or two weeks apart). Insert this page in to the inside front pocket of the participant's notebook. Also, keep a copy of the Lifestyle Balance Update page in your notes for each participant.

Fill in the activity session schedule on page 1 of Getting Started Being Active.

Introduce yourself and the other members of the local study team.

Greet the participant. Also welcome family member or other support person if present.

Hello. I'm delighted to meet you. My name is []. As you know, you've been assigned to the group in the SCI Weight Loss Program that will be making lifestyle changes to try to prevent diabetes. The lifestyle changes will be to lose weight through healthy eating and to be more physically active. We've called this group the

“Lifestyle Balance Program” because we’ll be helping you reach a healthy balance between what you eat and how active you are.

I will be meeting with you often during the next several years, so we will get to know each other very well. I’m looking forward to working with you as a team to make our time together a success. There are many people on the study team; we’re all resources for you.

Introduce the study team members, or use a video or photographs to introduce them if not present. Explain the role of each member of the team, and stress that during the upcoming years of the study, all of the members of the team will be available to support the participant.

Review the Standard Healthy Lifestyle Guidelines, *if not presented at randomization.*

At this point, I want to quickly go over some standard guidelines for a healthy lifestyle that all participants in the study receive. We give all participants this brochure [show the participant the Koop brochure], which is a good summary of the guidelines, and we talk with all participants about how to be more active [turn to pages 3-10; do not review them, however], eat a healthy diet [turn to pages 11-19], and reach and maintain a healthy weight [turn to pages 20-27]. Because you’re in the lifestyle change group, we will go over these topics in great detail in the coming weeks, so I won’t review them now. But this brochure is for you to take home as a source. Other members of your family might enjoy reading it, too.

We also talk with all participants about smoking and alcohol. Do you now smoke cigarettes?

Give the participant the Lifestyle Balance Notebook.

Here is the notebook we’ll use throughout the study. It’s yours to keep. At every session I’ll give you some handouts to put into the notebook and we’ll go over them together. Feel free to write notes or questions on the handouts, and take the notebook home. Just be sure to bring it with you to every session. Here is my name, address, and phone number for your records [give other team members’ phone numbers, as appropriate].

It’s very important that we stay in touch. Feel free to call me or stop in at the clinic whenever you have questions or need to talk. It’s also important to call if you cannot come to a session.

Discuss the participant’s initial reactions to being assigned to the Lifestyle Balance Program.

Some people who have been assigned to the Lifestyle Balance Program wanted to be in this group from the beginning; some hoped they would be assigned to another group in the study.

- **What do you think about being in the Lifestyle Balance Program?**

- **Are there some things about this group that seem good to you, and some things you're not so excited about?**

The participant may express disappointment about not being randomized to another arm of the study, fears of failing at the lifestyle intervention, memories of past failures at weight loss efforts, and so on. Recognize concerns, promote confidence that the participant can succeed, and give support.

If the participant is very negative, help him or her to identify *some* positive things about being assigned to this approach. Stress that the Lifestyle Balance Program is “state-of-the-art.” It has been carefully designed based on many research studies about the best ways to help people change.

Complete the work sheet “Remember Your Purpose” with the participant.

Emphasize the positive aspects of the intervention, relating them whenever possible to issues of personal value to the participant, and encouraging the participant to provide specific details, in images or words (such as the names of people) that can be recalled later as a source of motivation. Examples:

- Has the real potential to prevent diabetes.
- No drugs, no drug side effects.
- Will reduce his or her risk of heart disease and stroke.
- Will help him or her look and feel better, have more energy.
- Make her or his family and friends proud.
- Set a good example for children, spouse, friends, and community.
- Will contribute to scientific research findings that will then improve health care practices for the community.

Explain that you may review this work sheet with the participant later in the program as a source of motivation.

Receive an overview of the Lifestyle Balance Program.

As I said earlier, the Lifestyle Balance goals will be to:

1. Lose weight through healthy eating, and
2. Be more physically active.

We strongly believe that making these lifestyle changes and keeping them up over time will prevent diabetes in people like you who are at risk of diabetes.

The Lifestyle Balance program has been carefully designed. It is based on many research studies of the best ways to help people change.

In this program we will help you:

- **Learn the facts about healthy eating and being active.** Our staff is experts in nutrition, exercise, and helping people develop healthy habits. We will give you the most up-to-date and accurate information.

But knowing the facts, or what to change, isn't enough. You also need to know **how to change**. So we will help you:

- **Learn what makes it hard for you to eat healthy and be active.**
 - And learn **how to change these things so they work for you**, not against you.

For example, you'll learn how to:

- Find the time to be active.

[Review the rest of the items on the work sheet.]

We will also give you the **long-term support** you need to stick with the changes you make. We will be your **"coaches."**

Review the Lifestyle Balance Goals.

These are Lifestyle Balance goals:

1. **Lose 7% of your weight through healthy eating.** Your goal will be to weight xxx pounds or less.
2. **Do 2-1/2 hours of brisk, physical activity each week** (this would be like doing brisk exercise for 30 minutes on five days of the week).

We will help you to reach these goals one step at a time and keep them up over time.

We'll go over each of these goals in detail, and exactly what they mean for you, as we go along. You may also have your own specific goals you want to reach, but these are the goals for the study as a whole. I will do everything I can to help you reach the study goals, and so will the rest of the study team.

Refer to the Manual of Operations for how to respond to participants who have their own personal goals, for example, who want to lose less or more weight, who are already very active, or who wish to do less than 2-1/2 hours of activity. Briefly address their concerns, then move onto the study goals. For example:

- If the participant wants to lose less weight or be less active than the study goal: "We'll work toward this goal slowly, one step at a time. It's a safe and reasonable goal for you, and I'm very confident that you can do it."
- If the participant wants to lose more weight or be more active than the study goal: "Let's work toward this goal first. When you reach this goal, we'll talk about going further."

Discuss the rationale for the goals.

The Lifestyle Balance goals are **safe and can be reached**.

We will help you reach the goals by making:

- **Gradual (made one step at a time),**
- **Healthy, and**
- **Reasonable changes in your eating and activity.**

Nothing extreme. For example, you won't need to do very vigorous exercise, although you can if you want. "Being active" doesn't mean you need to be a marathon runner. We will just gradually increase your general activity and help you develop a more active lifestyle.

Reaching the Lifestyle Balance goals:

1. May prevent diabetes.

Research has shown that leaner and more active people are less likely to get diabetes. Also, moderate weight loss and physical activity have been shown to improve the body's use of insulin (the hormone that regulates the amount of sugar in your blood). This can reduce the chance of getting diabetes.

We believe that lifestyle changes can indeed prevent diabetes, if you make these changes and keep them up over time.

That's why you and I will work together to do everything we can to help you lose weight and be more active.

2. Reaching the Lifestyle Balance goals will also help you look and feel better and be more healthy in general. Research has shown that losing weight and being active can:

- Relieve tension, help you relax and sleep.
- Give you more energy, make it easier to get around (for example, if you're more active on a regular basis, your joints will be more flexible and you'll be less likely to injure your back).

Many of you may have health problems like high blood pressure or high blood cholesterol. Research has shown that losing weight and/or being active can:

- Lower blood pressure.
- Lower blood levels of LDL or "bad" cholesterol (the kind linked to the risk of having a heart attack or stroke).
- Raise blood levels of HDL or "good" cholesterol (the kind that reduces your risk of heart attack or stroke).

3. **In addition, reaching the Lifestyle Balance goals will set a good example for your family, friends, and community.**

Many of us live in a family or a culture that practices high-fat eating and inactivity. You will face a challenge as you work at doing things differently. But you will also set a good example of what it's like to live a more healthy lifestyle, which can be inspiring and encouraging to everyone around you.

I know that losing weight and being more active takes a lot of effort. **Changing behavior takes work.** It takes dedication and hanging in there and doing what needs to be done every step of the way.

We are here to help. I'll be meeting with you often, and I will do everything I can over the next four years to help you reach and stick with your Lifestyle Balance goals. I am confident that **you can do it!**

Discuss key aspects of the lifestyle coach-participant relationship.

It is very important that we work together throughout the study as a **team**. I will count on you to:

- **Come to sessions and bring your Lifestyle Balance notebook.**
Call 24 hours ahead if you must miss a meeting. For example, call before Monday afternoon if you must miss a Tuesday afternoon appointment.
- **Do your best to reach your eating and activity goals.** That includes doing home activities to practice what you learn.
- **Keep track of your eating and activity 7 days a week.** I'll talk with you more about this in a few minutes. **Be honest.** Don't try to "please" me. I will count on you to write down what you are really eating, and how active you really are, not what you think I want to hear or what would make me happy.
- **Keep track of your weight at home.** We will also weigh you here at each session. By weighing yourself at home, you will be able to see the pattern of your weight from day to day and see how your changes in eating and activity affect your weight.
- **Let me know if you have any problems.** Ask questions when you don't understand something. I am here to help and I need to know when you're having any difficulties. There's no such thing as a "stupid" question—it's *smart* to speak up when you have a question.

Some participants, because of their cultural heritage or personal history, may consider it rude to ask questions or to bring up difficulties. This is true, for example, of many Hispanics. With these participants in particular, be sure to express your acceptance and appreciation when they voice their questions and concerns.

- **Stay willing and open to change. Always "hang in there."**
 - We will sometimes run into problems, and I will count on you to hang in there and give it your best until we solve the problems together. This is a "can do" study. You can count on me to:
- **Go over your records of what you eat and your activity.**
Notice what you are doing well and what can be improved.

Noticing what you're doing **well** is one of my most important jobs. I will encourage you and build you up and appreciate your efforts.

- **Answer your questions.**

It's important that you feel free to ask me any questions you have, and I will get the answers for you. Please remember that the staff are experts, and our job is to make our expertise available to you in any way we can.

- **Be honest.**

We will both need to "say it like it is." I will count on you to be honest about how you are doing. And you can count on me to tell the truth about how I think you are doing and what I think needs to be done to solve any of the problems we run into.

- **Stand by you during hard times,** and

- **Believe you can reach your eating and activity goals.** We all need someone to believe in us when we are making changes for the better. I know you can do it, and when you get discouraged, I will be here to believe in you. **Always "hang in there" for you, and support and help you continually.**

Is there anything else you'd like me to do to help you? (Write any appropriate suggestions that the participant makes on the work sheet.)

Let's sign this as a way of remembering how we agree to work together.

Sign the agreement and have the participant sign it as well.

We want to be sure this program works for you. No two people are alike. So at different times during the study, you'll be able to choose *when* you want to focus on a certain topic, depending on what will be most helpful to you.

Overview the session topics.

This page shows you the topics for Sessions 1 through 16. As we've said before, you are welcome to invite a family member or friend to any or all of the sessions.

Session 1B: Getting Started Losing Weight

Objectives:

In this session, the participant who has chosen to focus on the weight loss goal first will:

- Learn the reason for self-monitoring foods eaten and the basic principles of self-monitoring.
- Be assigned self-monitoring of foods eaten and circling of high-fat foods; practice this.
- Receive weighing and measuring tools.

Review the reason for self-monitoring foods eaten and the basic principles of self monitoring.

You've decided to start with the weight loss goal. To help you lose weight, our goal is to help you to **eat healthy**. And healthy eating involves **eating less fat**.

This is because **eating too much fat is fattening (makes us fat) and is related to heart disease and diabetes**. (We'll go over this in more detail next week.)

The first step to eating less fat is to **figure out how much fat you are eating now**. To do this, I want you to **write down everything you eat and drink every day**. This is something we're going to do throughout the first 24 weeks of the study. It's the **most important part of changing your behavior**.

For right now, I just want you to write down what you ate, like you did during the run-in.

Keeping track of what you eat will help you and I see, in black and white:

- What foods you eat,
- How much you eat,
- When and where you eat, and
- How your eating habits change over time.

Your Keeping Track records will be the very basis for our working together. You and I will be the only ones to see them, so **spelling is NOT important**.

You can make up **abbreviations** or use your own shorthand if that makes it easier and faster for you to keep track, just so we both know what you mean.

Note: The use of abbreviations may also help those participants who have difficulty spelling feel less self-conscious.

What IS important is to:

- **Be honest.** That means to **write down what you really eat**, not just what you think will please yourself or me.
- Also, **be accurate.** It's best to write down what you eat as soon as possible after you eat it, because it's easy to forget. For example, count the number of slices of cheese you eat and write down the kind of cheese.
- And **be complete. Include everything.** The butter on the toast, the cream in the coffee, and the mayonnaise on the sandwich.

It may seem hard to write down all of your foods, especially at first. And it does take some time. But it's worth its weight in gold. **Being aware of what you are eating is the first step toward changing your eating habits.**

Assign self-monitoring of foods eaten and circling of high-fat foods.

To get you started I want you to do several things during the coming week. They're listed on this part of the work sheet called "To do next week." At every session you'll get a list of one or two things to do during the week. There are square boxes beside each item *[indicate boxes]* so you can put a check beside each one after you do it. That way you'll have a record of what you still need to do before the next session.

For this week, I want you to:

- **Write down everything you eat and drink every day.**

Use this "Keeping Track" book. Give the participant a Keeping Track book and indicate where in the book to record food intake.

Write down the time you eat something, the amount, and the name of the food or drink and a description. **Skip the other columns for now** *[indicate the grams of fat and calories columns]*. Use one line for each food. And **skip activity for now.**

- **Circle some of the foods or beverages you think are highest in fat.** Over time you will learn exactly what foods are high in fat. For now, just guess what some of the foods are. The idea is get you thinking about fat and looking for some of the high-fat foods in your meals and snacks.

Note: You do not want the participant to return with a book more than half filled with circled foods, which would be discouraging. This should be a positive beginning experience.

- Finally, be sure to **bring your completed Keeping Track books and your Lifestyle Balance notebook back with you** to every meeting.

Have the participant practice self-monitoring foods eaten and circling high-fat foods.

Let's take a minute to **practice Keeping Track on this page**. Think about a few of the foods you ate earlier today or yesterday. What was the first thing you ate? When did you eat it? Write the time here, the amount here, and the food here. Just skip the other columns.

Have the participant demonstrate. Be sure the participant understands what to do.
Do you think that food is high in fat? Just guess. If so, circle it.

Continue with several additional foods. Point out, as you go along, examples of accuracy (e.g., give brand name and type of food); honesty (e.g., include nibbles or very large amounts); completeness (e.g., include % fat of milk); and the use of abbreviations.

Just skip the section for physical activity.

Any questions?

Give the participant weighing and measuring tools.

If you want to, you can start to measure the amount of food you eat using these.

Get out the measuring tools.

Here are some **measuring cups and spoons** for you to start to use, just to get an idea of the amount of different foods you usually eat. We'll talk in more detail about measuring in the coming weeks.

For now, you might want to pour your breakfast cereal into the bowl you typically use, just as usual, and then measure the cereal before you eat it. Or put the amount of margarine you usually spread on toast onto the knife and measure it using the measuring spoons before you spread it. You can also use a glass measuring cup, if you have one at home, for liquids and a ruler for measuring things like pizza, pieces of pie, and cookies. This **scale** is for weighing meats and cheese (*briefly demonstrate how to use it*).

As I said, you don't need to measure amounts this week, unless you want to.

Any questions?

Discuss appointment schedule.

We will meet *every week* for the first 8 sessions. On this “Lifestyle Balance Update” page, which we’ll keep in the front of your notebook, I’ve used a pencil to write down some possible appointments for this same time and this same day of the week. Is this a good time for us to keep meeting?

If not, make changes to the penciled-in dates and on your copy of the Lifestyle Balance Update.

For sessions 9 through 16, we’ll meet *[explain the frequency that your clinic has decided to hold these sessions, whether every week or every other week.]* And then, after session 16, we’ll meet once every month or two months.

Session 2: Be a Fat Detective

Objectives

In this session participants will:

- Begin to graph weight and be assigned self-monitoring of weight.
- Learn the reason for and basic principles of self-monitoring fat grams.
- Receive the participant's fat gram goal.
- Practice finding foods in the Fat Counter and figuring out the number of fat grams in foods.
- Learn to calculate a running fat gram total for the day.
- Learn to use the Fat Bank (optional).
- If this is Session 4: Receive weighing and measuring tools. Also, develop an activity plan for the coming week (for most participants, a weekly total of 120 minutes).

To Do Before the Session

Review the participant's self-monitoring records from the run-in period, noting specific examples and general types of high-fat foods consumed.

Get the participant's "How Am I Doing?" graph for weight. The graph should show the participant's weight goal and expected rate of weight loss from randomization weight to the goal.

Using the participant's randomization weight, determine the participant's fat/calorie goals.
Refer to the Manual of Operations.

Get materials ready:

- Measuring cups, spoons, ruler, and scale.
- Fat Counter.
- Keeping Track book.
- Pages for the participant notebook.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities.

Review the participant's Keeping Track for food intake. Notice many good things, and make only one suggestion for improvement.

Were you able to write down anything this week about your eating?
What did you learn by Keeping Track? What difficulties did you have?

If the participant has not self-monitored, ask, "Tell me a little about that." Do your best to uncover some of the barriers that prevented the participant from Keeping Track without making him or her defensive. Problem solve with the participant to address the barriers.

Take a minute to page through the completed Keeping Track book, if available, from front to back. Comment briefly, as described below. (Also, keep the record until the next session or Xerox it. After the session, do a more careful review, make written comments, and return to the participant at the next session.)

Be positive and nonjudgmental. Emphasize what an important learning tool this will be throughout the study. Praise all efforts to keep track, no matter how small, and any level of accuracy or completeness. For example, praise any and all of the following efforts. The participant was able to [this list is for your reference, not to be reviewed with participants]:

- Record anything at all.
- Record something each day.
- Record throughout the day, each day.
- Note time of day.
- Describe kinds of foods (cuts of meat; parts of poultry; label information from packaged foods)
- Describe methods of food preparation: baked, broiled, steamed, stir-fried, fried, barbecued, etc.
- List additions to foods at the table: butter, margarine, cream, sugar etc.
- Give simple details about portion size: counts; cups; bowls; spoonfuls.
- Give actual weights and measures of portion size: package weight ounces, measuring spoons and cups, ruler measurements, food scale measurements.

Examples:

- "Great! I see here that you wrote down eating 13 cheese crackers with your soup."
- "It's really useful that you noted adding 2 teaspoons of butter to your beans."

Point out no more than one area for improvement, preferably starting with the most simple.

Example:

- "I see you were able to record all weekdays. Fantastic! In the coming weeks it will be useful for you to try and record on weekends too so we can learn about how your eating and exercise might be different then."

Weigh the participant. Introduce the How Am I Doing? Graph for weight and self monitoring weight at home.

Today's session is called "Be a Fat Detective" because we'll talk about how to become more aware of the amount of fat you eat and how that can help you lose weight through healthy eating.

Today's session is called "Be a Fat Detective" because we'll be talking about how to become more aware of the amount of fat you eat and how that can help you lose weight through healthy eating.

But before we talk about fat, let's begin today to **keep track of your weight** and your progress toward your weight loss goal.

In the first session we said that one of the study goals was to lose 7% of your weight, which means that, since your **starting weight was xxx pounds**, your **goal is to weigh xxx pounds**. Let's see what you weigh today.

Weigh the participant. See instructions in the Manual of Operations.

To keep track of your weight, we'll do two things. First, at every session we'll **mark your weight on this graph, called "How Am I Doing?"**

Insert the "How Am I Doing?" graph for weight into the front of the participant's notebook.

Here is your "starting weight," what you weighed when you first joined the study, and here is your goal weight. This line shows what a steady and gradual weight loss might look like for you. Of course, most people's weight goes up and down from week to week, and yours will probably do that, too, sometimes above this line, sometimes below it. Many people lose weight faster at first and then the rate levels off. We won't pay as much attention to each weight but rather to the pattern over time. We want you to stay under this line as much as possible and reach your goal weight by Week 24, or six months from now. That will be in *[name the month and mark on the graph at 24 weeks]*. After that we will help you to stay under your goal weight for four years. Maintaining your weight loss will be very important which is why we will teach you not only how to lose weight, but also how to keep it off!

Let's mark your weight for today on the graph.

Have the participant mark it on the graph. Provide help as needed.

When you weigh yourself at the center record your weight here...

Indicate the weight column on the back of the Keeping Track book, and circle the day(s) on which you want the participants to weigh themselves. See Manual of Operations for guidelines.

Introduce the rationale for and the basic principles of self-monitoring fat.

Now let's move on to the topic for today.

To help you lose weight, our goal will be to help you **eat healthy**. And **healthy eating involves eating less fat**, for several reasons.

- First of all, **eating too much fat is “fattening” (makes us fat). So by eating less fat, you can lose weight.**

In fact, fat is the most fattening of all the things we eat. Fat contains more than twice the calories (9 calories per gram) than the same amount of carbohydrate (starch or sugar) or protein (4 calories per gram). So **even small amounts of high fat foods are high in calories.**

Review the example on the worksheet (a lot of calories in a small amount of peanuts versus fewer calories in a large amount of popcorn) and/or other examples that are relevant to the participant's eating pattern.

- **Fat is also related to heart disease and diabetes.** Research has shown that eating a lot of fat can increase your cholesterol level. Cholesterol is one measure of the amount of fat in your blood. The higher your cholesterol, the greater your chance of having a heart attack. There is also some evidence that eating a lot of fat may increase your chances of getting diabetes.

For participants who want more information:

The recent Surgeon General, C. Everett Koop, MD, had this to say about the importance of eating healthy: "If you are among the two out of three Americans who do not smoke or drink excessively, your choice of diet can influence your long-term prospects more than any other action you may take." In other words, healthy eating is one of the most important steps you can take to improve your health.

And in his recent report to the nation, the Surgeon General named eating less fat as our country's number one dietary priority, more important than sodium, sugar, or additives. In fact, all of these important national organizations recommend eating less fat: the National Heart, Lung, and Blood Institute, the American Heart Association, the American Diabetes Association, the American Dietetic Association, and the American Cancer Society.

What kind of foods do you eat that are high in fat?

Let's look at some of the high-fat foods you circled in your Keeping Track. [Write on the work sheet a few of the foods that the participant correctly circled as high in fat.]

What kind of foods do you eat that are high in fat? [If the participant doesn't mention any high-fat foods, briefly look with the participant at this or her self-monitoring records from the run-in period. Write on the work sheet some of the high-fat foods noted.]

Make some general points about the food groups or types of food that tend to be high in fat, such as:

1. Meats (Meats contain both fat that you can see and fat that you can't see.)
2. Dairy foods (whole milk, regular cheese, ice cream) (Many Americans get most of their fat from meats and dairy products, including cheese.)
3. Snacks (such as potato chips)
4. Butter, margarine (Many people add fat to foods to flavor them.)
5. Gravy, mayonnaise
6. Baked goods (such as cookies, cake, muffins)
7. Fat added in cooking (oil, lard, shortening) such as deep-fat frying (fried chicken, French fries, doughnuts).

Keep in mind that the purpose of this list is **not** to give the participant detailed information about where fat is found in foods. Rather, the purpose is to begin to show them that many different foods that they eat are high in fat and to provide a rationale for self-monitoring. The facts about where fat is found in foods should come later as a byproduct of their own discovery through self-monitoring.

These are the kinds of foods you will have to watch out for as you become a "fat detective." They are also the kind of foods that are widely available, tempting to many of us, and they may even be traditional foods in your family or culture.

Many people aren't aware that most of the fat we eat (70% of it, in fact) is hidden in foods.

For example, fat is hidden in:

- The marbling of meats,
- Baked products,
- Sauces, and
- Batter coatings on deep fried foods.

Here's an example. *[Review the example on the worksheet.]* That's a lot of fat, a total of 22 teaspoons or about 1 entire stick of butter or margarine.

The best way to learn how much fat is in food is to **keep track of the amount of fat you eat every day**.

You will need to adapt the following section depending on the participant's literacy level, willingness to self-monitor, and comprehension of the self-monitoring process. If this is Session2, some of the following will be a review of points made at the last session; when possible, make these points using examples from the abbreviated self-monitoring the participant did during the previous week.

The first step is to:

1. **Write down everything you eat and drink in your Keeping Track books.**

This is something we're going to do throughout the first 24 weeks of the study. It is the **most important part of changing your behavior**.

Keeping track of what you eat will help you and I see, in black and white:

- What foods you eat,
- How much you eat,
- When and where you eat, and
- How your eating habits change over time.

Your Keeping Track records will be the very basis for our working together. You and I will be the only ones to see them, so **spelling is NOT important**. You can make up **abbreviations** or use your own shorthand if that makes it easier and faster for you to keep track, just so we both know what you mean.

Note: The use of abbreviations may also help those participants who have difficulty spelling feel less self-conscious.

What IS important is to:

- **Be honest.** That means to **write down what you really eat**, not just what you think will please yourself or me.
- Also, **be accurate**. It's best to write down what you eat as soon as possible after you eat it, because it's easy to forget. For example, count the number of slices of cheese you eat and write down the kind of cheese. Measure portions and read labels (we'll talk in more detail about these things next week).
- And **be complete. Include everything**. The butter on the toast, the cream in the coffee, and the mayonnaise on the sandwich.

It may seem hard to write down all of your foods, especially at first. And it does take some time. But it's worth its weight in gold. **Being aware of what you are eating is the first step toward changing your eating habits.**

2. **Figure out how much fat is in every food and write it down.**

To do this, you will need to:

1. Figure out the amount of the food you ate.
2. Look up each food in the Fat Counter, which is a book I'll give you that lists foods and the grams of fat in each one.
3. Compare the amount of food YOU ate with the amount in the Fat Counter to see how much fat you ate. And third,

3. **Add up the fat grams you eat during the day.**

I'll show you how to do each of these things in just a minute.

Give the fat gram goal.

Everyone in the Lifestyle Balance Program gets a fat gram goal or "budget." It is based on body size and the amount of calories needed to lose weight. So everyone has a different goal.

Your fat gram goal or "budget" is to stay under xx grams of fat each day. You can think of it as a budget because you need to stay *under* it every day. *[Fill in the blank with the participant's fat gram goal (refer to the Manual of Operations).]*

A gram is the way fat in food is measured. A gram is a unit of weight. One paper clip weighs about 1 gram. *[Note: Be careful not to go into too much detail here because some participants may be easily confused by the differences between grams of weight and grams of fat.]*

We don't expect you to stay under your fat gram goal right away or be able to stay under it every day. It may be hard to reach your fat gram goal at first. For now, just try to **get as close to your goal as you can**. During the next few weeks, we will teach you how shop for food and cook and serve it so that it is easier for you to reach your goal. Overtime we'll work together so that you can consistently stay *under* your fat gram goal.

Give the participant the Fat Counter. Demonstrate and practice how to use it and food labels to figure out how much fat the participant eats. *[If this is Session 4, also give the participant measuring tools.]*

This is a Keeping Track of Fat "practice page." Let's write down some of the foods you ate yesterday and figure out the grams of fat in those foods.

Write on the work sheet a variety of foods that the participant ate yesterday. If possible, include both high- and low-fat foods and several foods with portion sizes that might require some calculation on the part of the participant. Show the participant how to look each food up in the Counter and calculate the number of fat grams in the amount that the participant ate.

Exactly how you do this will vary from participant to participant. The key is not to overwhelm those participants who may find calculations difficult and confusing. Assure these participants that you will continue to help them with this in the upcoming sessions and that the **important thing for now is to begin looking foods up in the Counter and getting an idea of the amount of fat in different foods and in various serving sizes.**

As you look foods up in the Counter, give the participant the weighing and measuring tools and make the following points:

Here are some measuring cups and spoons for you to start to use, just to get an idea of the amount of food you usually eat. **Next week we'll go over measuring in more detail and practice it together.**

For now, you might want to pour your breakfast cereal into the bowl you typically use, just as usual, and then measure the cereal before you eat it. Or put the amount of margarine you usually spread on toast onto the knife and measure it using the measuring spoons before you spread it. The glass measuring cup is for liquids. This scale is for weighing meats and cheese (briefly demonstrate how to use it). The ruler is for measuring things like pizza, pieces of pie, and cookies.

Here are some things to keep in mind **when you use the Fat Counter.**

If you can't find a food:

- Look for one that is the most like that food. (Don't assume that a food doesn't contain fat because it's not listed in the Fat Counter.) For example, use nut bread for zucchini bread.
- Write the name of the food in the back of your Fat Counter. There is a section there for listing additional foods. Then ask me about it next week, and I will help you find the fat grams.
- If you are having trouble figuring the grams of fat:
- Just write down the food and the amount you ate. I will help you figure the fat grams when you come in.

If you make a recipe:

- For many recipes, you can simply write down how much of each ingredient you ate. For example, in a stew, write down the amount of each ingredient that was in the amount you ate. For example, how much beef you ate, how much carrots, and so on. Include any fat that you used in cooking.

- If you cook from recipes often, bring in some favorite recipes next week. I will help you count the grams of fat in them.

An optional handout is available on counting fat grams in more complicated recipes. We think that this handout should be saved for a later session, and at this point it would be more appropriate to ask the participant to bring in any recipes he or she uses often and help the participant estimate the fat grams. Remember that the participant is self-monitoring, not recording dietary data for nutrient analyses, and the point is to learn to distinguish high fat from lower-fat foods and make dietary changes toward the fat gram goal.

If you do use the handout at some point, use it to demonstrate how to count the fat grams in one of the participant's own recipes, rather than alone.

The bottom line for this week is to just get started and do your best. If you run into any problems, I'll help you with them next week.

If you eat a packaged food:

- Look on the label for the fat grams. (Even if it is listed in the Fat Counter, the grams on the label are more accurate.) First, find the Nutrition Facts on the label, and look at the serving size. Is this the amount you ate? And look at the total fat grams per serving.
- What if you eat a larger serving than is listed on the label? You will be eating more fat grams than are listed on the label.

Review the sample label on the work sheet. Be sure that the participant understands that the serving size on a label may be very different from what most of us consider a serving.

Demonstrate and practice how to add up fat grams during the day.

Some participants may be confused and overwhelmed at this point because of difficulties with calculations. Do **not** review adding up fat grams with these participants until the beginning of the next session. Instead, simply use the "Adding up the fat grams" worksheet to practice again how to look up fat grams and calculate the number of fat grams in the amount eaten by the participant. As before, tailor this to the participant's skill level.

The final step in keeping track of fat is to add up the fat grams you eat during the day.

There are two ways you can do this in your Keeping Track.

[Turn to Adding Up the Fat Grams work sheet.] Imagine that this is your Keeping Track.

Let's write in some of the foods you ate last week, the amounts you ate, and the grams of fat. In the Grams of Fat column, you can put a slash mark after the number of grams of fat and write down a "running total" (keep adding up the grams of fat throughout the day).

Demonstrate or have the participant calculate several running totals.

A running total is like a subtotal or running balance in a checkbook. The purpose of keeping a running total is so you know just how much fat you've eaten as you go along. You can use this to plan what foods you choose for the rest of the day. For example, "What should I have for lunch? Well, I've eaten x grams of fat so far. My fat gram goal is x grams. So I'd better eat less than x grams of fat for lunch to stay under my fat goal for the day." This is like using a budget to manage how much money you spend.

Another way to add up the fat grams is to use what we call the Fat Bank, these columns that look like rulers. The left column is the Fat Budget. The right is Over Budget.

I'll show you how to use it.

Have the participant do as much of the following as possible. Provide help as needed.

- a. **Your fat goal is x grams. Find that number on the Fat Budget column and put an arrow beside it.** Cross through all of the notches above your goal.
- b. **Then fill in or cross through one notch for each gram of fat you eat.** Start at your fat budget and go DOWN.

Demonstrate or have the participant cross through the notches for the breakfast foods.

You can easily see about how much fat you have left for the day in your budget.

- c. **If you cross through all of the notches in the Fat Budget column, start at the bottom of the Over Budget column and go UP.** This will let you see how much over your fat gram goal you are.
- d. **Write the total fat grams for each day on the back of your Keeping Track booklet** (show the participant where the totals should go). This will help us both to see at a glance how you've done during the entire week.

Have the participant complete the grams of fat, running total, and Fat Bank columns for the rest of the foods on the sample. Also, show the participant where to transfer the total fat grams for the day to the back of the Keeping Track book. Again, be careful not to overwhelm the participant.

Changing the way we eat is a gradual process and it will take time. I don't expect you to be perfect. During the next few months you will learn many different ways to help you eat less fat. For now, I want you to be the best fat detective you can be, looking for fat everywhere. And just do your best to **come as close to your fat gram goal as you can.**

Do you have any questions?

Participants should leave this session aware that:

1. We are more interested in their efforts to be honest and complete about their eating habits than to present us with picture-perfect Keeping Track records, and
2. We consider self-monitoring a very important tool and expect everyone to do some monitoring.

Assign home activity.

For next week:

- Keep track of your weight.
Weigh yourself at home every at this time of day.
Record your weight on the back of the Keeping Track book.
- Keep track of what you eat and drink.
Write down everything you eat and drink in your Keeping Track books.
 - Do this every day, as soon as possible after you eat.
 - Be honest.
 - Measure portions as much as you can and start reading labels.
 - And be sure to include everything you eat.

Use the Fat Counter to figure out how much fat is in what you ate, and write it down in your Keeping Track books. Keep a running fat gram total throughout the day. Try using the Fat Bank, too. Come as close to your fat gram goal as you can.

If this is Session 4:

Keep track of your physical activity, as you have been. And be a little more active this week-- your goal is
(for most participants, it will be 120minutes).

Session 3: Three Ways to Eat Less Fat

Objectives:

In this session, the participant will:

- Review self-monitoring skills, and learn in more detail how to weigh and measure foods, by estimating the amounts of selected high-fat foods, actually measuring the amounts, and then calculating the fat grams.
- Learn three ways to eat less fat.
- Make a plan to eat less fat.
- If this is Session 5: Develop an activity plan for the coming week (for most participants, a weekly total of 150 minutes).

To Do Before the Session

Get materials ready:

- Measuring cups and spoons, glass measuring cup, scale, and ruler.
- Fat Counter.
- Pages for participant notebook.
- Optional handouts that are appropriate for a specific participant (e.g., the blank “Menu Make-Over” work sheet).
- Food models or actual foods for weighing and measuring demonstration. Include a selection of common high-fat foods, plus enough food models of teaspoons of fat (1teaspoon = 4 grams of fat)-or test tubes filled with measured amounts of shortening — to show graphically the fat content of the foods. If possible, choose actual foods that you know the participant eats often. If this isn’t possible, try to use food models that weigh close to what the actual food would weigh to avoid confusing the participant (for example, regarding the weight of various portion sizes of meats). For the actual foods, weigh or measure them in advance. For the food models, tape the amounts on the bottom. Some foods that may be suitable:

To weigh on the scale:

- 3 oz (after cooked) regular (25% fat) hamburger patty (keep frozen) to weigh on scale. 19 grams of fat (equivalent to 5 teaspoons of fat).
- 4 ounces cheddar cheese, thinly sliced by a deli (keep refrigerated). 28 grams of fat(equivalent to 7 teaspoons of fat).

To measure in metal or plastic measuring cup, teaspoon, tablespoon:

- 3 teaspoons of soft margarine in a tub (keep refrigerated). 12 grams of fat (equivalent to 3 teaspoons).
- 4 tablespoons of oil in the bottom of a frying pan, plus same amount in a small jar or bowl. (Ask the participant to guess the amount in the pan first, then bring out the jar or bowl of oil for the participant to measure with a tablespoon). 48 grams of fat (equivalent to 12 teaspoons of fat).

- 1-3/4 cups macaroni and cheese made from a mix (keep refrigerated). 34 grams of fat (equivalent to 8 teaspoons).
- 3 cups of “butter-flavored” movie popcorn. 29 grams of fat (equivalent to 7teaspoons of fat).

To measure in the glass measuring cup:

- 1-1/2 cups of whole milk in a large cereal bowl (keep refrigerated). 12 grams of fat(equivalent to 3 teaspoons of fat).

Weigh the participant. Mark weight on the How Am I Doing? Graph for weight.

If the participant has lost weight, congratulate him or her, but don't go overboard. Stress the fact that he or she must already be making some changes in **behavior**.

If the participant has not lost weight, mention it but stress that little by little as she or he makes behavior changes, the numbers on the scale will change.

Check if the participant weighed himself or herself at home. Discuss the fact that the two scales may differ. Patterns of change should be similar on both (if gain weight on clinic scale, home scale should show a weight gain, also).

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. [If this is session 5, graph activity, also.]

Were you able to write down anything this week about your eating?

What did you learn by Keeping Track? What difficulties did you have?

Were you surprised by the amount of fat in some foods?

How did using the Fat Counter go?

Were you able to keep a running total of fat grams or use the Fat Bank?

How close did you come to your fat gram goal?

Refer to the script for the ‘Be a Fat Detective’ for guidelines on how to review the Keeping Track records.

Review self-monitoring skills using the Fat Counter, weighing and measuring tools, and actual foods or food models.

We've given you measuring cups and spoons and a scale because **weighing and measuring foods is important**. Today we're going to start with something a little more “hands-on” than we've done so far and practice weighing and measuring together. First, let me go over some details about how to use the cups and scale and so on. You may be doing these things already.

Metal or plastic measuring cups and spoons

Use these for solid foods like margarine or mashed potatoes. Fill the cup or spoon and then level it off before you record the amount.

Demonstrate how to level.

Leveling can make a big difference. For example, even two extra tablespoons of granola on top of a cup that hasn't been leveled will add about 3 grams of fat.

Glass measuring cup (demonstrate this, although the study does not provide one)

Use a glass measuring cup, if you have one at home, for liquids like milk or soup. Pour the liquid in the cup, then read the line at eye level. If you read it from above, your eyes can fool you.

Demonstrate measuring liquids and reading the amount from eye level. Use any liquid. Water is fine.

Scale

The best way to measure meat and cheese is on a scale. Even a small amount can make a big difference in fat. Scales can measure very small amounts.

Demonstrate the use of the scale by weighing an actual food or food model. Have the participant weigh another food or food model. Make sure the participant can use the scale and read the results.

It's important to **weigh meats after they are cooked**. They lose about a quarter of their weight in cooking. So 4 ounces of raw meat weighs about 3 ounces when it's cooked. Three ounces of meat is about the size of a deck of cards or your palm, minus the fingers.

When you weigh cheese, you'll notice that one slice might look like another but not weigh the same. For prepackaged slices, you can check the label for the weight.

Most people are surprised when they begin to weigh and measure foods. Our eyes can play tricks on us.

Here are some common high-fat foods that someone might easily eat in a day.

Show the participant food models or actual foods for common high-fat foods. Review the instructions on the work sheet and have the participant complete the chart except for the column "Teaspoons of Fat." If possible, use some actual foods that the participant eats often and observe the participant using the

weighing and measuring tools so you can check her or his technique. Note: It may be helpful to repeat this activity at various points during the intervention, particularly after the Progress Review during Session 7 or 8, 12, and 16, as a way to review measuring skills and demonstrate the importance of accurate portion estimation.

Were you surprised by the actual amounts? Even small mistakes in estimating amounts can make a big difference in the fat grams.

Eventually you will get better at judging food amounts by looking. **For now, weigh and measure foods as often as you can.**

Last week we talked about the fact that most of the fat we eat is hidden in foods (70%, in fact). For example, fat is hidden in:

- The marbling of meats,
- Baked products,
- Sauces, and
- Batter coatings on deep fried foods.

Let me show you what the fat in these foods would look like if we could see it as teaspoons of butter, margarine, or oil. *[Fill in the last column of the worksheet and if possible, illustrate using food models of teaspoons of butter or test tubes of measured amounts of shortening.]* That's a lot of fat, a total of x grams and x pats (or x sticks) of butter or margarine altogether *[note: one stick of butter or margarine = 1/2 cup or 24teaspoons]*. Pretty amazing.

Introduce the three ways to eat less fat.

Many different kinds of foods are high in fat, but there are only three basic ways to eat less fat.

1. **Eat high-fat foods less often.** *[Review the example on the work sheet.]*
2. **Eat smaller amounts of high-fat foods.** Cutting back even a little can make a big difference. *[Review the example.]*
3. **Eat lower-fat foods instead.**

In the coming months, you'll discover a number of ways to "eat lower-fat foods instead." Here are a few examples of the difference you can make. *[Review the examples on the work sheet, including the warning about the calorie content of low-fat or fat-free products. Use other or additional examples if they would be more relevant to the participant's eating pattern.]*

Review the “menu make-over.”

These menus show examples of small changes that make a big difference in fat grams saved. These are examples of the different ways to eat less fat, not menus for you to follow.

You will make your own food choices to reach your fat gram goal.

Review the examples on the worksheet. Mention that potato chips appear in both menus, and explain that there are no “good” or “bad” foods (the participant can eat any food in a small amount now and then and still reach his or her fat gram goal).

A blank “Menu Make-Over” work sheet is available if at this or other sessions the participant would benefit from recording personal examples of high-fat menus and corresponding make-overs.

Assign home activity.

Let's focus now on what you can do next week.

- Keep track of your weight and what you eat. Keep a running fat gram total throughout the day, and try to stay under your fat goal (budget).
*[If this is Session 5] And continue to keep track of your physical activity. This week be a little more active, for a total for the week of. [Fill in the blank. For most participants, the goal will be **150 minutes**.]*
- Make a plan to eat less fat and follow it.

Let's make the plan right now using this chart. First, write down 5 foods you eat that are high in fat. These should be foods that you eat often (not, for example, birthday cake that you eat only rarely). Now circle one of these foods and pick one of the three ways to eat less fat from that food.

Complete the rest of the work sheet with the participant, and assign the questions at the bottom as part of the home activity. Stress that the plan to eat less fat should be specific and realistic.

Session 4: Healthy Eating

Objectives:

In this session, the participant will:

- Discuss how eating less fat fits into the overall context of healthy eating.
- Review the Food Guide Pyramid and its recommendations, including to lower fat.
- Compare the participant's eating pattern to the Food Guide Pyramid.
- Review more examples of ways to eat lower-fat foods instead of high-fat foods.
- Be introduced to the importance of eating more grains, vegetables, and fruits.

To Do Before the Session

Get materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Poster of Food Guide Pyramid.
- Optional handouts that may be appropriate for a specific participant (for example, one on low-fat recipe substitutions for participants who cook from recipes often).
- Individual samples of low-fat foods to taste (optional).

Weigh the participant. Mark weight on the How Am I Doing? Graph for weight.

If the participant has lost weight, congratulate him or her, but don't go overboard. Stress the fact that he or she must already be making some changes in **behavior**.

If the participant has not lost weight, mention it but stress that little by little as she or he makes behavior changes, the numbers on the scale will change.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. [If this is Session 6, graph activity.]

If this is Session 6:

Were you able to follow your activity plan from last week?

Discuss any barriers and problem solve with the participant. Graph on the How Am I Doing? Graph for activity.

What did you learn by Keeping Track last week? What difficulties did you have?
Were you surprised by the amount of fat in some foods?

How did using the Fat Counter go? Did you keep a running total for fat grams?
Did you follow your plan to eat less fat? How close did you come to your fat goal?

Refer to the script for the 'Be a Fat Detective' for guidelines on how to review the Keeping Track records.

Discuss how eating less fat fits into the overall context of healthy eating. Introduce the Food Guide Pyramid.

In the past few weeks, we've talked quite a bit about eating less fat. **Eating less fat is essential to losing weight. It's also one important part of healthy eating in general.** Today we're going to talk about some of the *other* parts of healthy eating. We'll look at your overall eating pattern to see how healthy it is and how you might improve it.

What exactly is "healthy" eating?

One part of healthy eating is the way you eat.

- **A regular pattern of meals is important.** Try to eat 3 meals each day. This will keep you from getting too hungry and losing control.
- **Eat slowly.** You will digest your food better if you take small bites and chew your food well. Also, you'll be more aware of what you are eating and more aware of when you are full. Try pausing between bites, putting down your utensils, and enjoying the taste of your food and the company who may be present.
- **Don't worry about cleaning your plate.** The greatest waste of food is to eat more than you want or need. Practice serving yourself smaller portions to begin with.

Another part of healthy eating is what you eat. One way to define what's included in a healthy eating pattern is by using the **Food Guide Pyramid**. Have you heard of the Food Pyramid? *[Tailor the following discussion based on what the participant already knows about the Food Pyramid.]*

The Food Pyramid is a **general guide to healthy eating** that's based on the latest findings about nutrition and health.

Turn to the Food Pyramid work sheet and point out the base of the pyramid.

The pyramid image is used because at the bottom is the **foundation**, the largest part of the structure, what the rest of the eating pattern is built on.

The foundation of the Food Pyramid is grains, or the **bread, cereal, rice, and pasta group**. These foods should be the main part of your diet. A healthy eating pattern includes **6 to 11 servings** from this group. A generation ago, many families built their meals around meat: the "meat and potatoes"

eating style. Now we know that most Americans eat too much fat and protein, and much of it comes from big servings of meat.

So in the Food Pyramid, the foundation is not meat, but rather breads, cereals, and other grain foods.

After naming the group and stating the recommended number of servings, ask the participant the following questions for every group except fats, oils, and sweets. As you do so, write on the work sheet a few examples of low-fat choices for each group, including serving size.

If possible, use example foods mentioned by the participant. Keep the discussion simple and tailor it to the individual (use examples that match the participant's eating preferences and ethnic background). A Food Pyramid handout on the next page will provide more details for participants who want them about the types of foods and serving sizes in each group. Ethnic variations are available. Do not review the entire Food Pyramid if it would be overwhelming to the participant.

1. **What are some low-fat foods that would fit into this group? What do you think would be considered one serving of these foods?**
2. **Can you think of any high-fat foods that would be in this group? These would be the foods for you to avoid.**
3. For the breads and cereals group: Many people think bread and potatoes and other starchy foods are high in fat, but actually it is the fat added to them in cooking or at the table that makes them high in fat. Potatoes are a good example: plain potatoes are low in fat, but by adding butter or sour cream, they become high in fat.
4. For the meats group: Nuts are included in this group (for example, peanut butter). All nuts are very high in fat. And many meats are high in fat, too. Americans tend to eat too much meat. We used to think we needed to eat a lot of meat to get enough protein, but now we know that Americans tend to eat *too much* protein. The Food Guide Pyramid recommends only two to three servings from the meat group and the portion size for a serving of meat is only 2 to 3 ounces. (Use a food model to illustrate this.) The meats group also includes dried beans. Have you tried dried beans, like kidney beans in chili? Unlike most meats, dried beans are high in protein but low in fat, unless you cook or serve them with added fat.
5. For the milk group: Some people have trouble drinking milk because it gives them gas, bloating, and diarrhea. Is that a problem for you? If so, milk products that are lactose-free may help you get rid of these problems.
6. The smallest part of the Pyramid is at the top, fats, **sweets, and alcohol**. These foods should be eaten **only in small amounts**. In general they don't provide vitamins and minerals, and they are high in calories, "empty" calories. (Remember that fat contains 9 calories per gram and alcohol contains 7 calories per gram, compared to carbohydrates and protein at 4 calories per gram. Small

amounts of sweets won't add many calories, but many sweets, like cakes and chocolate, are also high in fat.)

- a. What are some lower-fat alternatives for foods in this group?
- b. What are some of the high-fat foods to avoid?

Have the participant compare his or her eating pattern to the Food Pyramid recommendations.

Let's look at one or two days from your Keeping Track book and compare what you ate to the guidelines given on the Food Pyramid. *[Turn to Rate Your Plate page.]* Let's start with breakfast and look at how many breads, cereals, rice, and pasta you had.

Move on throughout the day's record, and check off on the Rate Your Plate chart each serving from the food groups. Don't worry about being precise. This is not a self-monitoring record but a general guide to healthy eating. Clarify in simple terms any questions that come up regarding serving sizes.

- Consider one fat serving to be: one teaspoon of butter, margarine, oil, or regular mayonnaise; 1 tablespoon of cream cheese or salad dressing; or 10 peanuts.
- Consider one sweets serving to be: ½ cup of ice cream, 1 small cupcake or piece of cake, or 2 small cookies.
- If the participant drinks alcohol, explain that a) the recommendation is that if you choose to drink alcohol, do so in moderation, and b) alcoholic beverages are high in calories.
- Consider one serving to be one can (12 fluid ounces) of beer (150 calories), one glass (5 fluid ounces) of dry wine (115 calories), or 1.5 fluid ounces (one "shot") of liquor (105 calories). Mixers, such as tonic or a regular soft drink, add more calories.

Continue with a second day if appropriate.

What could you do to better match the Pyramid?

It looks like you could eat more *[vegetables]*. Let's think about tomorrow. If you want to eat 3 to 5 servings of vegetables, how could you do it?

Write example food choices and amounts on the work sheet, total the servings, and compare to the goal number of servings. E.g., 2 servings of salad with nonfat salad dressing for lunch, 1 cooked vegetable and 1 serving salad with nonfat salad dressing for dinner = 4 servings. **Emphasize the importance of increasing grains, vegetables, and fruit.** It is not necessary to complete the rows for every food group.

Provide more examples of ways to "eat lower-fat foods instead."

Last week we talked about the three ways to eat less fat, one of which is to "eat lower-fat foods instead." The Food Pyramid and "eating lower-fat foods instead" work together. Here are some

examples. *[Review the guidelines on the work sheet, highlighting those that are particularly relevant to the participant and reviewing examples from all of the Food Pyramid groups.]*

Do you **cook from recipes**? Or does your spouse? What are some examples?

If the participant does a *great deal* of cooking from recipes, review the guidelines on the optional handout, **Build a Better Recipe**, highlighting those that are particularly relevant to the participant. If the participant only uses recipes occasionally, save the optional handout for a later session because this session is so full of information.

If the participant wants help in lowering the fat in a favorite recipe, have the participant bring the recipe to the next session and modify the recipe with the participant at that time.

Don't review recipe substitutions or modifications at all if the participant seldom cooks from recipes.

For some participants, recipe modification may be helpful as a small part of several future sessions, and it may be important to include other family members who cook for the participant. Regardless, remember that this is an early session and don't try to do too much at this point. Demonstrations of low-fat cooking can be done in future sessions during the maintenance phase of the trial.

Assign home activity.

For next week, I want you to:

- Continue to Keep Track of what you eat *[if this is Session 6, also assign Keeping Track of activity.]*
- For this week only, we're adding one more simple form, the same one we used today to Rate Your Plate. Use the two pages after this one to go over your Keeping Track records and compare what you ate to the Food Pyramid. *[Review the instructions on the forms.]*

Completing the Keeping Track booklet is much more important than completing the Rate Your Plate form. If the participant seems very reluctant to complete the Rate Your Plate forms, mention that you can complete them together at the next session and that the priority is to Keep Track.

Also, answer these questions before our next meeting:

- Did you make any changes during the week to better match the Food Pyramid? If yes, what were they?
- What problems did you have? How did you solve them?

Any questions?

Session 5: Move Those Muscles

Objectives:

In this session, the participant will:

- Receive the Lifestyle Balance activity goal.
- Discuss why the activity goal is important.
- Discuss current level of physical activity.
- Be encouraged to participate in the Lifestyle Balance activity sessions.
- Identify other activities equivalent to brisk exercise that the participant enjoys.
- Discuss the importance of wearing appropriate clothing.
- Develop an activity plan for the coming week (for most participants, this will be a total for the week of 150 minutes of activity) that includes the Lifestyle Balance activity sessions and other moderate activities that the participant enjoys.

To Do Before the Session

Get materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Schedule and map for the supervised activity sessions.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities.

Were you able to come to the Lifestyle Balance activity sessions last week?

Were you able to do something active on 3 to 4 days during the week?

Be positive and nonjudgmental. Praise all efforts to be more active, no matter how small. If the participant did not attend the sessions and/or did not do at least some activity during the week, ask, "Tell me a little about that." Do your best to uncover some of the barriers that prevented the participant from attending or being active without making him or her defensive. Problem solve with the participant to address any barriers. Stress again the important reasons for attending the activity sessions, particularly at the beginning of the study, and for taking steps to be active to some degree on a regular basis.

If this is Session 5 (the last session was "Healthy Eating"):

How did Keeping Track go last week? Did you "Rate Your Plate?" Did you make any changes during the week to better match the Food Pyramid? If yes, what were they? What problems did you have? How did you solve them?

Review and comment on the participant's self-monitoring records. If the participant did not complete the "Rate Your Plate" form, complete the form for one or two days with the participant. Praise all improvements, no matter how small. Problem solve with the participant to address any barriers.

Weigh the participant and graph.

Introduce the Lifestyle Balance activity goal.

So far you've focused on losing weight through healthy eating. This week and next week we'll focus on the other goal of the Lifestyle Balance program: being more active.

The Lifestyle Balance activity goal is to **do a total of 2-1/2 hours of physical activity each week.**
This will burn about **700 calories per week.**

Assess participant's current level of activity.

Now, before we can make an activity plan for you, I need to know **how active you are now.**

The purpose of the following discussion is to get a general idea of how active the participant is and to get the participant talking about his or her personal preferences and experiences with physical activity. Record the participant's answers on the work sheet, and make notations of pertinent details in the participant's progress notes so that you will be able to understand the situations (cues) that promote or derail a participant's physical activity. For example, if a participant has been able to exercise regularly in the past, primarily by doing it at lunch with a coworker, then this valuable piece of information can be highlighted from the start and the participant can be helped to arrange his/her environment accordingly.

- **Do you do any kind of regular physical activity that lasts at least 10-15 minutes?** (Examples: work out at a health club, etc.) Where do you do these activities? With whom?
- How many **times each week** do you do these activities? And when you do, **for how long are you usually active?**
- Have you done any **activities in the past** that you no longer do? Why did you stop? Have you thought about starting to do them again?

If the participant names one or more activities, use them as a starting point when planning for next week.

- **What do you like or dislike about being active or being inactive?** (Record.)

Provide the rationale for the activity goal.

I want to be sure you understand why being more active is so important. **Being more active will:**

- **Help you feel and look better.**
Being active can:

- Improve your mood,
- Counter depression and anxiety,
- Give you more energy,
- Help reduce stress,
- Be a way to meet new friends,
- Help you sleep better,
- Improve your self-esteem (help you to feel better about yourself in general),
- Improve your muscle tone and body measurements.

Many people report that they simply **feel good** when they're more active, and they really miss it if they've been active for a while and then stop.

- Regular physical activity will **make you more physically fit**. It will:
 - Strengthen your heart, lungs, bones and muscles,
 - Make your joints more flexible,
 - Reduce pain and injuries,
 - Make it easier for you to do your daily work, like carrying groceries,
 - Make it easier for you to play with your children or grandchildren.
 - **Help you lose weight and keep it off.**
 - Research has shown that the best way to lose weight is to eat a healthy diet **and** be more active. A combination of both is also the best way to keep weight off.

In addition to helping you lose weight, be more fit, and feel better in general,

- Physical activity will **lower your risk for heart disease, some kinds of cancer, and may help prevent diabetes.**

Being more active:

- Raises HDL cholesterol (the good cholesterol),
- Lowers triglycerides, and
- Lowers blood pressure if it is elevated.
- Being more active also lowers blood sugar by making the body more sensitive to insulin. This reduces the risk of diabetes.

Describe the Lifestyle Balance activity sessions.

It's not easy to start being more active. We are here to help. Some things that can help you are to:

- **Come to the Lifestyle Balance activity sessions!**

List other activities that the participant enjoys that can be counted toward the activity goal.

- It will also help if you **plan activities you LIKE to do.**

After all, the point is to make physical activity a regular part of your lifestyle, and that will never happen unless you enjoy the activities you do. Exercise should be intense **enough to breathe heavier than usual and to consider that you are working hard, but not so fast that you can't carry on a conversation or have trouble breathing.**)

Many kinds of activity are good,. **What other activities might you like to do?**

Write on the work sheet **only the activities the participant should count toward the activity goal**, that is, those that are equivalent to brisk exercise, as indicated in the Lifestyle Intervention.

Manual of Operations. Don't review the list of activities in the Manual of Operations with participants, but use it as your own reference only.

From time to time, the activities you like may change. Just let me know, and we can make changes to this list.

Develop an activity plan for the coming week.

Now let's make a **plan for next week**.

- During the week I want you to **be active for**.

Fill in the blank on the work sheet with the total number of minutes of activity per week (for most participants, this should be **60 minutes**).

For example, you could do xx minutes of activity on 3 different days of the week. We'll gradually increase this over the next three weeks until you're up to 2 ½ hours of new activity per week.

- **Include a friend or family member if you would like.** Some people like to be active alone, as a time to do something special for themselves. But many people find it helpful to be active with someone else. Is there anyone you would like to invite to exercise with you?
- **Include the Lifestyle Balance activity sessions.**
- And remember to **plan activities you LIKE to do.**

Okay. Let's write down the activities you will do on which days of the week. How many minutes will you do them? It should be for **at least 10 minutes**.

- Also, **keep track of your physical activity every day** *[or, if this is Session 5, keep track of your weight, eating, and activity]*. Use your Keeping Track books. Keeping track will help us both to know how you are doing from week to week.

Show the participant where in the Keeping Track book to self-monitor activity. If this is Session 2, you have already shown the participant how and where to self-monitor activity, so the following will be somewhat redundant.

Write down what the activity was and how long you did it. Also, if you're exercising and know the distance in miles, write that down too if you want to. Use one line for each time you're active, even if it's the same kind of activity. For example, if you go around the block at 8:00 in the morning and again at 7:00 in the evening, write both down separately.

It's also important to **record only the amount of time you were actually *doing* the activity**. By that I mean don't include the time when you may have been taking a short break. For example, if you exercised and after 10 minutes you ran into a friend and stopped to talk for 5 minutes before exercising for 10 more minutes, you should only write down 20 minutes of exercise, not 25 minutes. The same is true for when you go swimming. If you are in the water for 60 minutes but only swim laps for 10 of those minutes, then you were only active for 10 minutes and that is what you should write in your Keeping Track.

Session 6:

Being Active: A Way of Life

The script for this session is written as if the participant has been relatively sedentary before this time. Use your judgment to change your presentation of the session for those participants who have already been fairly active.

Objectives:

In this session, the participant will:

- Begin to graph activity.
- Discuss time as a barrier to activity.
- Learn two different ways to find the time to be active.
- Discuss lifestyle activity.
- Discuss ways to prevent injury and receive handouts on how to do some simple stretches and when to stop exercising.
- Develop an activity plan for the coming week (for most participants, this will be a weekly total of 90 minutes).

To Do Before the Session

Get materials ready:

- Keeping Track book.
- Pages for participant notebook, including individualized How Am I Doing? graph for activity.

Weigh the participant. Graph the weight in the participant's notebook.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities.

Last week we made a plan for your physical activity. **How did it go?**

Review the participant's Keeping Track records for activity. Praise any physical activity that was done, whether or not the participant reached his or her weekly goal.

If this is Session 6: Also review the participant's dietary self-monitoring and progress toward fat and/or calorie goals and weight loss.

Did you attend any of the activity sessions?

Emphasize again the importance of these sessions, especially at the beginning of the program. If the participant did not attend, try to uncover and address anything that got in the way.

Did you have any trouble Keeping Track of your activity? *[If "yes," review.]*

Graph participant's activity.

Every week we'll **mark your activity on this graph** *[show the participant the How Am I Doing? graph for activity]*. We'll use the graph to see your progress over time and how you are doing compared to your activity goals.

Mark the participant's recorded activity from last week on the graph, or if possible, have the participant do so.

Discuss barriers to activity.

It's important that we try to **solve any problems you're having following your activity plan**. Let's take last week. Did anything get in the way of your plan for activity?

Discuss whatever problems the participant brings up and brainstorm possible solutions. Consider any additional difficulties, such as upcoming cold weather, that the participant may face in the next few weeks and make plans to cope with these. Keep the examples relevant to the present or very near future. Examples:

Problem: Children.
Solution(s): Get a baby sitter or other family member to watch them.
Include the children in the activity (e.g., going for a exercise).

Problem: Hot weather.
Solution(s): Exercise early or late in the day when it is cooler.
Exercise indoors

Problem: Cold weather or rain.
Solution(s): Wear appropriate clothing.

Optional participant handouts are available on various barriers to activity, such as cold or hot weather. Give the participant only those that are relevant at this time.

Discuss time as a barrier.

One of the most common problems is lack of time. Everyone's busy these days.

But you can find the time to be active.

Here are two different ways.

- **Set aside one block of time for planned activity every day.**

Make being active a predictable part of your daily routine, like taking a shower may be a predictable part of your morning.

Use an example that is particularly relevant to the participant's lifestyle. For example, businesspeople may relate to an example of making a "standing appointment" for physical activity. Mothers may relate to an example of planning time to read a bedtime story every night to a child.

When can you set aside 20 to 30 minutes to do an activity you like? Are you a morning person? Or would you enjoy getting out for exercise during lunch? How about after dinner?
[Complete the work sheet.]

Some people can't find one big block of time to be active. Either their schedules vary a lot from day to day, or they're so busy that there isn't a 20-30 minute period that's free on most days. For some people, this might be the case during certain seasons of the year, for example, during the fall when after-school schedules begin to get hectic for their kids.

In these situations, it's usually easier to use a different approach.

- **Be on the lookout during the day for 10 to 15 minutes of free time. Use the time to be active.**

For example, you might be able to take a 10-minute break between meetings at work and go for exercise. Then later, take another 10-minutes to exercise after lunch. In the evening, take 10-minute exercise before you pick your son up from soccer practice. By the end of the day you've done 30 minutes of activity.

In a way, you really can't "plan" for these times, but you can think ahead about when to be on the lookout for them. Or seize the moment! Sometimes all the best planning in the world falls apart. There's still the "spontaneous approach." On some days you might look at the work or housekeeping you have ahead of you and realize, "I'm not going to finish all of this today, no matter what I do." So plan your exercise and JUST GO!

Can you think of any times during the day when you have 10 or 15 free minutes?

[Complete work sheet.]

Discuss lifestyle activity.

We've been talking about the kind of activity you will be recording in your Keeping Track books, whether you do it in one block of time or at several times during the day. Another important kind of activity is called "**lifestyle activity**." It involves **making active choices throughout the day**. It's hard to record this kind of activity, so **we aren't asking you to write it down in your Keeping Track books**. But it is just as important as what you do record.

An example of an inactive choice is when you shop, park your car as close as you can to the entrance to the store. An active choice is to park your car further away and wheel. This may only take a minute or so to do, but every minute of activity has an impact on your overall health and it adds up to a "more active you."

Our parents, and especially our grandparents, didn't have a choice about being active throughout the day. They were active because they had to be. There weren't elevators in every building. They had no car or only one car for the entire family. They had no phone or only one phone and so they ran up or down the stairs to answer it. They did the dishes and laundry by hand. It was simply their way of life. By contrast, most of us now have so many conveniences that our lives are almost guaranteed to be inactive unless we **consciously make active choices**.

What are some active choices you could make during the day? What are some inactive choices you could limit?

Add examples to the chart. Possibilities include:

- Wheel to a nearby store rather than driving.
- Go for a 2-minute exercise session during TV commercials (especially food commercials!).
- Do stretching exercises while watching TV.

Turn inactive time into active time.

Many people say they have no time exercise but they watch several hours of television in the evening. **Try cutting your TV time in half and turn it into exercise time**. Or be active while you watch TV. Lift weights, or exercise with your arms.

At first, you may think of exercise as a way to relax after a long day. But when you get used to it, you'll discover that exercise is a great way to relax and unwind, and you may feel much more rested and refreshed than you would have had you spent that time on the couch in front of the TV.

Discuss ways to prevent injury and give the participant some handouts on simple stretches and when to stop exercising.

- Build up your activity *slowly*. Start and end each session *slowly*. Exercise at a less intense pace is a fine way to warm up and cool down. If you want, you can also do some simple stretches like those on these handouts.

These handouts also tell you what to do if you get a cramp or a muscle strain or pull and when to stop exercising. So look the handouts over at home and we can discuss any questions you have at the next session.

Note: Don't review these handouts during the session. Most participants will simply be wheeling as their form of physical activity, so it is not necessary to emphasize stretching. Just suggest that they start and end their exercise at a slower pace. For those participants who begin doing more intense activity later on, review these handouts at that time.

If a participant starts doing stretches, make sure they do not include stretching time in their 2 1/2-hour goal.

Develop an activity plan for the week.

Now let's make an activity plan for next week.

- The goal is to do a little more than last week, for a weekly total of. *[Fill in the blank on the worksheet. For most participants the goal will be **90 minutes** of activity per week.]*

Try setting aside one block of time, or plan to use several 10-15 minute periods during the day. Include the activity sessions, and be sure to plan activities you LIKE to do. *[Complete the chart.]*

- Also, **keep track** of your physical activity every day. *[If this is Session 6, assign weight and dietary self-monitoring also.]*

Record only the time when you are **doing** the activity. (That is, don't include breaks.) And **don't record activities that last less than 10 minutes**. *[Give the participant a Keeping Track book.]*

- **Include lifestyle activity throughout the day.**
You won't record this, but it is still very important. What active choices do you plan to make during the week?*[Record on the blank line.]*

Next week we'll talk about the lifestyle activity you did.

Any questions?

Session 7: Tip the Calorie Balance

Objectives:

In this session, the participant will:

- Discuss how healthy eating and being active are related in terms of calorie balance.
- Discuss how calorie balance relates to weight loss.
- Review the participant's progress so far in terms of a) changes made in fat/calorie intake and activity, and b) weight change. Discuss how this relates to calorie balance.
- Develop an activity plan for the coming week.
- If weight loss is less than what is expected, make a plan for the coming week to either self-monitor calories or follow a low-calorie meal plan, or both.

To Do Before the Session

Review some of the participant's past Keeping Track records. Make brief notes of some of the positive changes the participant has made to eat less fat and be more active.

For participants who have not lost weight as expected or have gained weight:

Determine the participant's daily calorie goal (refer to the Manual of Operations).

Make sure the participant's How Am I Doing? graphs for weight and activity are up to date.

Have materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Meal plans appropriate for the participant's calorie goal. Tailor to the participant's food preferences as much as possible before the session.

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity? (Graph activity.)

If this is Session 8 (the last session was "Take Charge of What's Around You"):

Were you able to get rid of the problem food cue and add the positive cue for being more active?
What problems did you have? What could you do differently next week?

If this is Session 7 (the last session was “Being Active: A Way of Life”):

Were you able to make the active lifestyle choices you had planned?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Explain how healthy eating and being active are related in terms of calorie balance.

Everything we've covered so far fits together. It fits together because of what's called the "calorie balance." That's what we'll talk about today.

We've said many times that the Lifestyle Balance Program involves **two kinds of lifestyle changes**:

1. Healthy eating. This includes eating less fat and more grains, vegetables, and fruits, and
2. Being active.

These changes are important in and of themselves. They may prevent diabetes and lower your risk of other diseases. They are also important because they're **both related to weight loss** and that's because of what's called "**calorie balance**."

Calorie balance is the balance between the calories (or energy) you take in by eating and the calories (or energy) you use up by being active.

When you eat **food**, you take in calories or energy.

- Calories in food come from **fat, carbohydrates (starches, sugar), protein, or alcohol**. Other ingredients in food, like vitamins, minerals, and fiber, don't have calories. (For example, green leafy vegetables are mostly vitamins, minerals, and fiber--and they have very few calories).
- The **number of calories in any food you eat depends on what's in that food. Fat is the most concentrated in calories, with 9 calories per gram**. That's more than twice the number of calories in starches, sugars, or proteins, and even more than alcohol. So foods that are high in fat are high in calories. That's one important reason why our emphasis has been on eating less fat.

For example, many people think of meats as being “pure protein” but actually most meats contain protein plus a lot of fat, which is where most of the calories in meats come from.

Calories also measure the energy you **use up**.

- You use calories **for just staying alive** (like breathing) and **by any activity** you do.
- The **number of calories you use** in a certain activity depends on several things, including the type of activity, the amount of time you are active, and how much you weigh (basically, the amount of energy used is determined by the amount of weight carried and the distance over which you carry it. When you wheel for a distance of a mile, for example, you are carrying a lot of weight (your body) over a long distance (1 mile).

If the participant is doing a different type of planned activity, check with the exercise physiologist on staff to convert minutes or distance into calories.

Explain how calorie balance is related to weight loss.

Your **weight** is determined by the **balance between food (calories in) and activity (calories out)**.

Let's look at four ways the calorie balance can work.

1. Your weight can **stay the same**. In this case, "calories in" from food equal "calories out" from activity. Food and activity are at about the same level on both sides of the scale.
2. Second, you can **gain weight**. In this case, "calories in" from food are higher than "calories out" from activity. Either calories have increased or activity has decreased or both. The balance has tipped this way *[indicate direction of balance]*.
3. Third, you can **lose weight**. "Calories in" from food are lighter than "calories out" from activity. You've eaten less food (by less I mean fewer calories, not less in volume--remember, we said early in the program that you can actually eat more food for the same number of calories by eating lower-fat foods), or you've done more activity, or both. The best way to lose weight is to do **both** at the same time and **really tip the balance** this way *[indicate direction]*.
4. And finally, you can reach a **new balance at a new weight**. You have developed new food habits and new activity habits and they are balanced again. This is what happens when you lose weight and keep it off. You've reached a new balance over time.

The important thing to **remember** is that:

- **Food and activity work together** to determine how much you weigh.
- To lose weight, it's **best to eat less and be more active**. That way, you are changing both sides of the energy balance at once. **By TIPPING the balance, you can lose the weight you want.**
- Then, over time, you can reach a new balance at a new, lower weight. We will help you to **make the changes part of your lifestyle, so you will keep the weight off.**

Explain calorie requirements for weight loss.

How much do you need to tip the balance in order to lose weight?

The number of calories you need to eat, or the amount of activity you need to do, varies from person to person. But in general, there is a formula we can use. It's based on two facts:

- **1 pound of body fat stores about 3,500 calories**, and
- **Slow, steady weight loss (1 to 2 pounds or so a week) is the best way to lose body fat.** (Quick losses of large amounts of weight can mean that water or muscle are being lost rather than fat, and that's unhealthy.)

So **to lose 1 pound in a week, you need to tip your energy balance by 3,500 calories** in the week. Or 500 calories each day for 7 days. Or to lose 1-1/2 pounds in a week, you need to tip your energy balance by 5,250 calories in the week. Or 750 calories each day for 7 days. For a 2-pound weight loss per week, you need to tip the balance by 7,000 calories in the week, or 1,000 per day.

Again, for weight loss, the best way to tip the balance is to change both food **and** activity.

Review the participant's progress so far in terms of a) changes made in fat/calorie intake and activity, and b) weight change. Discuss how this relates to calorie balance.

Now let's take a minute to review some of the **changes you've made so far** on both sides of the balance.

- First, **what changes have you made to be more active?** We've talked about increasing both planned activity, the kind you've been recording in your Keeping Track books, and lifestyle activity, like taking the stairs instead of an elevator.

Briefly record on the work sheet some of the changes made by the participant. Praise and encourage the maintenance of these changes.

- **What changes have you made to eat less fat (and fewer calories)?** We've focused on eating less fat because fat is the most concentrated source of calories.

Briefly record on the work sheet some of the changes made by the participant. Praise and encourage the maintenance of these changes.

Have these changes tipped the calorie balance?

The answer is in how the scale has responded.

- At the **start of the Lifestyle Balance program, you weighed ...** (*refer to the How Am I Doing? graph for weight at randomization visit and record that weight on the work-sheet*)
- **Your weight now is...** (record on work sheet).

- And **we expected your weight by this time would be ...** (*record the weight indicated on the graph by the expected weight loss line at this week*).

So you have ...

Check one of the three boxes on the work sheet. Be as positive as possible, stressing the accomplishments the participant has made so far, no matter how small, and express your confidence in the participant's future success.

- **Stayed at the same weight, or gained weight.**
 - To lose weight, you need to try something else to tip the calorie balance. We'll work together to find out what will work better for you.
- **Lost some weight, but not as much as expected.**
 - Good. You've made some progress.
 - To lose more weight, you need to try something else to tip the calorie balance *further*.
- **Lost as much weight as expected (or more).**
 - Great! You've tipped the calorie balance.
 - If you keep tipping the balance, you will keep losing weight.

Develop an activity plan for the coming week.

For next week:

- Continue to keep track of your weight, eating, and activity.
Be active for _____ .

Fill in the blank on the work sheet, depending on how active the participant has been until this point. For most participants, *if this is Session 8*, the goal should be **150 minutes** per week; *if this is Session 7*, the goal should be **120 minutes** per week.

By doing more activity, you will use more calories.

As before, try setting aside one block of time each day, or look for 10 to 15 minutes that open up during the day and use them to be active. Include the Lifestyle Balance activity sessions. And plan other activities you **LIKE** to do. *[Complete the chart.]*

- **Make active lifestyle choices throughout the day.** As we've said before, every minute of activity is helpful. So keep moving as much as you can.
What are some of the active choices you plan to make this week? *[Fill in the blank.]*

If weight loss has not been as expected, make a plan for the coming week to either self-monitor calories or follow a low-calorie meal plan, or both.

The following is a requirement for participants who have not lost as much weight as expected. It is an option for successful participants who want to lose more weight or express an interest in learning more about the calorie content of foods.

- **And to tip the calorie balance further, one of two things will be helpful:**
 - **Keep track of calories every day, just like you've done for fat grams.**

Sometimes it isn't enough to just look at fat grams. You may be eating some foods that are relatively low in fat but still high in calories. (For example, many of the new fat-free frozen desserts and cookies are just as high (or higher) in calories than the original versions because of added sugar.) Or you may be eating large enough portions of some foods that the calories are adding up. By keeping track of calories, you'll learn which foods are higher in calories and find ways to save calories. So this week, we want you to look up the calories in every food you eat, just like you've been looking up the fat grams.

Try to stay under calories each day. You should lose weight if you eat that number of calories. Also,

- Watch out for the foods that are high in calories.
- Be sure to record *everything*.
- And watch portion sizes.

Or it might be most helpful for you to:

- **Follow a meal plan for calories per day.**

A meal plan is a model or good example of what to eat. A meal plan will:

- **Show you exactly what foods and amounts to eat.** You won't be faced with a lot of decisions and temptations about food.
- A meal plan will also **make it easier for you to record what you eat.** In fact, if you follow the meal plan *exactly*, you won't need to record anything.

Which do you think would be most helpful, keeping track of calories or following a meal plan? Or would you like to try both?

Check the box or boxes on the work sheet.

- If applicable, give the participant the appropriate meal plans. Tailor the meal plan to suit the participant's food preferences, and answer any questions or concerns the participant has regarding following the meal plans as closely as possible for the coming week. Present the meal plan as a flexible model from which the participant can develop an individualized eating style, rather than as

a rigid prescription. (See How to Use the Lifestyle Balance Meal Plans for further information on how to introduce the meal plans to participants.)

- With some participants, you may need to practice calorie monitoring using an example and/or briefly double-check and correct portion estimation skills using food models.

For the rest of the study, we'll keep working together to bring you closer to your weight loss and activity goals. **We'll keep trying to tip the calorie balance and see how the scales respond.** Over time, you'll reach a new balance at your goal weight and then we'll work together to help you maintain that weight.

Note: The following explanation is for only those participants who express interest in how their calorie goal has been calculated. Do not give this text to participants.

Question: How did you determine the number of calories I should be eating to lose weight?

Answer: The number of calories you need for weight loss depends on many things, including how active you are, how old you are, and so on. But we can make a good guess and then see how the scale responds. We like to begin by estimating what you ate when you entered the program.

1. Estimate of what you ate when you started:

Starting weight x 12 = calories/day (estimate)

2. A slow, steady weight loss of 1 to 2 pounds per week is the best goal.

- To lose 1 pound, you must eat 3,500 calories less. If you want to lose 1 pound in 1 week, you would need to eat 500 fewer calories each day for 7 days.
- To lose 2 pounds, you must eat 7,000 calories less. If you want to lose 2 pounds in 1 week, you would need to eat 1,000 fewer calories each day for 7 days.

We recommend that heavier people aim to lose 2 pounds per week, and that thinner people lose 1 pound per week. No one should eat fewer than 1,000 calories/day.

3. Estimated calories at start: calories/day for maintenance

To lose 1 pound per week, subtract 500 to get calories/day.

To lose 2 pounds per week, subtract 1000 to get calories/day.

So your daily calorie goal for weight loss is _____.

Session 8:

Take Charge of What's Around You

Objectives:

In this session, the participant will:

- Learn about food and activity cues and ways to change them.
- Mentally search the participant's home, work place, and where the participant shops for food, looking for problem food cues and discussing ways to change them.
- Learn ways to add positive cues for activity and get rid of cues for inactivity.
- Develop an activity plan for the coming week (150 minutes per week).

To Do Before the Session:

Get materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Optional handouts that may be appropriate for specific participants (for example, the "Am I Really Hungry?" sign to post on the refrigerator door).

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity? (Graph activity.)

Did you "Rate Your Plate?" Did you make any changes during the week to improve the way you eat (eat more slowly, follow a regular pattern of meals/snacks)? Did you make any changes to better match the Food Pyramid? If yes, what were they? What problems did you have? How did you solve them?

If the participant did not complete the "Rate Your Plate" form, complete the form for one or two days with the participant.

Were you able to make the active lifestyle choices you had planned? Keep track of calories and stay under your calorie goal and/or follow the meal plan (*if applicable*)? Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Introduce the concept of eating and activity cues.

Today we're going to talk about **taking charge of what's around you**, or **how to make what's around you support your Lifestyle Balance goals** to lose weight by healthy eating and to be more active.

First, we'll talk about cues for eating, and later, go on to activity cues.

What "cues" you (or makes you want) to eat?

- Of course, one reason we eat is because of **hunger**. But what about those times when you have an "appetite" or desire to eat without physically being hungry?
- You might eat because of **what you're thinking or feeling**. For example, you might eat some ice cream because you feel lonely, bored, or happy.
- You might eat because of **what other people say and do**. You might eat chips at a party because a friend offers them to you.
- Or you might eat because of **the sight or smell of food, or**
- **Certain activities that make you think about food** (like watching TV or reading magazines). This is what we'll focus on today. In later meetings we'll talk about eating in response to thoughts, feelings, or what other people say and do.

The **sight of food** is one of the most powerful food cues. For example, you may see a carton of ice cream in the freezer and soon you'll be eating ice cream, even though you're not hungry. The **activity of watching TV** is also a powerful food cue for many people. You may turn on the TV and find yourself eating potato chips, even though you're not hungry.

Another example is **eating popcorn at the movies**. Do you eat popcorn when you go to the movies?

If not, probe for another example that is relevant for the participant, such as eating hot dogs at a sporting event or buying cookies after passing a bakery. Use the example in the discussions that follow.

Why do you eat popcorn in that situation? Do you think it's because you're hungry?
Most likely, it's because eating popcorn at the movies is a **habit** for you.

When you respond to a food cue in the same way over and over again, you build a habit.
The food cue becomes paired with the way you respond, and your response becomes more and more automatic.

Let's say that since childhood, you've gone to the movies many, many times, and you've eaten many boxes of popcorn there. Now you find yourself eating popcorn whenever you go to the movies, even though you're not hungry. You responded to the cue (going to the movies) in the

same way (buying popcorn), over and over again. Buying popcorn became a habit. And since it's a habit, it may be hard for you to sit through a movie and not have popcorn.

Food cues and eating habits are not harmful by themselves. But they can be a problem if they get in the way of your efforts to eat less fat and calories.

Discuss two ways to change problem food cues and habits.

How can you change problem food cues and habits?

1. One of the best things you can do is to **stay away from the food cue. Or keep it out of sight.** For example, you may not be willing to stop going to the movies, but you can stay away from the concession stand. If you keep going to the movies and don't let yourself have popcorn, slowly you will stop thinking about popcorn. The connection between the movies and the popcorn will have been broken.
2. Or you can **build a new, healthier habit. Practice responding to the cue in a healthier way.** An excellent way to support yourself as you do this is to **add a new cue that helps you lead a healthier life.** For example, you might take a package of sugar-free gum with you when you go to the movies. When you enter the theater, take out a piece of gum. After a while, you will connect going to the movies with chewing gum.

It's important to remember that **it takes time to break an old habit or build a new one.** Change doesn't happen overnight. If you wanted to stop eating popcorn at the movies, you would need to see a lot of movies without popcorn. Eventually, you will enjoy the movie and forget about the popcorn.

Note: Some participants will find it hard to accept the idea that cues in the environment make them want to eat certain things. Try to find some ways (for example, as in the bullets below) to show the participant that there are many food cues around us all the time and that this phenomenon is so common that we are usually unaware of how powerful it is.

These ideas are powerful, and they work. Also, they're nothing new. People use them every day, sometimes very consciously and sometimes without even thinking about it. Some examples:

- Food companies deliver samples of new breakfast cereals right to your door by mail. They know that if they can get the food into your house, you'll eat it.
- For generations, mothers have put leftover snacks in the front of the refrigerator so their teenagers are more likely to eat them before the foods spoil.
- Supermarkets put new products on the shelves that are the easiest to see and reach.

In this session, we want to help you learn to make changes in what's around you to encourage healthy eating and being more active.

Identify specific food cues at home that are a problem for the participant. Discuss ways to change them.

Let's talk about **some of the problem food cues in your life and some ways you can change them.**

Note: A few common food cues are listed at the top of the second work sheet. Do not turn to this yet.

Let's start with **where you live**. Imagine that we've just opened the front door. We have a video camera, and we start taking a video of what's in the room. Which room would it be? Do you see any actual food in the room? Do you see anything else that might make you think about eating, like a TV or a comfortable chair? What is a change you could make to stay away from that cue or to build a new, healthier habit?

Move from room to room ("Are there other rooms that are a problem for you?"), asking for cues and discussing possible ways to either stay away from the cue or to build a new, healthier habit. If the participant has no response, refer to previous Keeping Track records and/or turn the page in the participant's notebook to the list of common problem food cues and ask if one or two of the examples apply to the participant (possible solutions are given below). Don't give too many examples. Some will undoubtedly come up at future sessions and can be addressed in detail at that time. The purpose of discussing specific examples is to make the "remember" points that follow of relevance to the participant.

Living room (or bedroom)

Cue: *TV (or computer, telephone).*

Solution(s): One way to break the connection between eating and the TV is to make it a rule never eat while watching TV (or on the computer or phone).

Keep an exercise band near the TV.

Keep a pack of sugar-free gum near the TV (or computer). Allow yourself only gum while watching TV (or working on the computer).

Cue: *Candy dishes (for serving candy, chips, and nuts) on an end table.*

Solution(s): Don't buy the candy, chips, or nuts.

If you must buy these foods, hide them. Keep them out of sight.

Kitchen

Cue: *High-fat/calorie foods, **especially those that are ready to eat**. In the freezer (e.g. ice cream), refrigerator (e.g., cheese, lunch meats, whole milk, pie), kitchen*

cupboards (e.g., cookies, chips), or on counter tops (e.g., cookie jar, food packages).

Solution(s): Stop buying these foods altogether.
Store them out of sight, in a brown bag or other unattractive, opaque container.
Make them hard to reach.
Keep lower-fat/calorie choices easy to reach, in sight, and ready to eat.
Examples: Fresh fruits, raw vegetables (already washed and prepared), non fat dips, pretzels, low-fat popcorn, diet drinks.
Limit high-fat/calorie choices to those that require preparation.

Cue: *Foods you are cooking or leftovers, on the stove or counter.*

Solution(s): Make it a rule not to eat while cooking.
Taste foods only once, then rinse your mouth with water or a breath mint immediately.
Rinse off any utensils used in food preparation immediately after each use.
Ask someone else to taste the food.
Put leftovers away **before** meals.
Ask someone else to put the leftovers away.
Put leftovers in individual serving containers right away, and freeze them for future meals.

Dinner Table

Cue: *Serving dishes or packages of food on the table during meals.*

Solution: Serve foods from the kitchen.
Store food only in the kitchen. Put packages away immediately after use.

Cue: *Large dinner plates (or large glasses, bowls, serving spoons and forks).*

Solution(s): Serve yourself small portions using a smaller plate or bowl. Or ask someone who is supportive to do so. Spread the food attractively over the plate.

Cue: *Leftovers on plates.*

Solution(s): Remove your plate from the table as soon as you're finished.
Don't eat the food that your children leave on their plates.

Identify specific food cues at work that are a problem for the participant. Discuss ways to change them.

Let's do the same thing with **where you work**. Are there any things on your way to work, around you at work, or on your way home that have become paired with eating high-fat/calorie foods?

Cue: *Fast-food restaurant (or bakery, hot dog stand, candy store, etc.) on the way to or from work.*

Solution(s): Take a different way to work.
Make it a rule to never eat in the car.

Cue: *High-fat/calorie foods in public areas* (doughnuts or high-fat coffee creamers near the coffee pot, candy on secretary's desk, etc.).

Solution(s): Stay away from those areas.
Buy or make your own coffee in a different place.
Bring a low-fat/calorie snack to share with co-workers.
See if there's a way to keep these foods out of sight (other co-workers may appreciate it, too).

Cue: *High-fat/calorie foods on your desk, in your desk drawer, or in your locker.*

Solution(s): Don't bring high-fat/calorie foods to work. Keep low-fat/calorie snacks like apples, raw carrots, pretzels, low-fat popcorn, or diet beverages on hand instead.
Make it a rule not to eat at your desk.

Cue: *Vending machines.*

Solution(s): Stay away from the vending machines.
Bring a low-fat/calorie snack from home. Or buy juice or pretzels, if available in the machine. Ask a friend to go get them for you, so you won't be tempted by the other foods.

The important thing to **remember**, whether you are at home or at work, is:

1. **Keep high-fat/calorie foods out of your house and work place. Or keep them out of sight.**
Out of sight is out of mind.

Keep lower-fat/calorie choices easy to reach, in sight, and ready to eat.

Examples: Fresh fruits, raw vegetables (already washed and prepared), non fat dips, pretzels, low-fat popcorn, diet drinks.

2. **Limit your eating to one place.** Where do you eat most of your meals at home? Limit all eating to this place. When you are hungry, go to this place to eat. This will help you to distinguish between hunger and other cues to eat.

At work, a particular table in the cafeteria or kitchen area may be a good choice. Do not eat at your desk or computer. This is an open invitation to become distracted from eating.

3. **When you eat, limit other activities.** The rule is simple: No TV, driving, or talking on the phone while you are eating. Focus on enjoying the meal. In the future, these other activities will not cue you to eat.

Identify specific food cues while shopping for food that are a problem for the participant. Discuss ways to change them.

Finally, let's take the video camera to **where you shop for food**. Move around the store as you usually do. What do you see that's a problem for you?

You don't have as much control over what foods are in the grocery store as you do over what foods are in your house. But you do have some control. Here are some tips:

- **Make a shopping list ahead of time.** Make it a rule not to buy anything that's not on the list.
- **Don't go shopping when you're hungry.** Have a low-fat/calorie meal or snack first.
- **Avoid sections in the store that are tempting** to you, if possible. For example, go down a different aisle to avoid the bakery.
- **Ask the grocery store manager to order low-fat/calorie foods** that you want to buy. Remember, that is their business, to please you, the customer.
- **Don't be a slave to coupons.** Only use the coupons that are for low-fat/calorie foods, not for high-fat foods.

Identify specific positive cues for activity that the participant could add to his or her home.

Now let's turn to **physical activity**. For most people, there are many things around them that lead to being inactive. For example, after dinner, you may automatically position yourself in front of the TV. This is because the end of dinner and TV have been paired together many times in the past. But remember, you do have a choice. You could just as easily choose to exercise after dinner.

If you have been inactive, you probably have many cues around you that are associated with inactivity and few that would cue you to be active. To be active regularly, it's important to add positive activity cues to your life. Over time, the cues will become paired with being active, and you will develop new activity habits that will become more and more automatic.

What are some positive activity cues that you could add to your life? Let's pick up our imaginary video again, and start with **where you live**. What could you add to the living room that would prompt you to be active?

Move from **room to room**. Mention a few examples from the handout and add some that are particularly relevant to the participant.

In the living room or bedroom:

- Keep exercise equipment in sight, not in the closet.
- Hang an activity calendar and graph of your activity in a visible place.
- Keep an exercise band near the TV. (Why not make TV a positive cue?)
- Hang a photo or poster of people being active or of outdoor scenes in a visible place.
- Subscribe to a health or exercise magazine. Keep it in a visible place.
- Buy a home exercise video and leave it on the coffee table or on the TV.
- Put a note on the TV reminding you that a half hour of TV time could be used for exercise instead.

In the kitchen:

- Post motivational photos, outdoor scenes, or reminders to be active on the refrigerator.

In the bathroom:

- Post a reminder on the mirror before breakfast.

Identify positive cues for activity that the participant could add to his or her work place.

What are some positive activity cues that you could add to your work place? Let's pick up our imaginary video again. *[Mention a few examples from the handout and add some that are particularly relevant to the participant.]*

- Put your exercise band in a visible place in your office.
- Put a note on your office door reminding yourself to exercise during your lunch break before eating.
- Set an alarm on your watch to remind you to exercise.
- Make a regular, daily appointment with yourself to be active. Write it in your date book. Keep your appointments with yourself—they are as important as your other appointments.

Emphasize two cues that can prompt activity either at home or work.

- Set up a **regular "date" to be active with a friend or family member.** When she or he arrives at 7:00 for exercise, you'll probably go even if you don't feel very energetic.
- **Use a timer or alarm on your watch to remind you to be active.**

Discuss some ways to remove cues for inactivity.

Another approach is to remove the cues for being inactive.

- **Watch less TV.** Keep the TV behind closed doors in a cabinet. Or get rid of your TV. Or be active while you watch TV (for example, use your exercise band or system).
- **Don't leave things in a pile around the house.** They remind you to keep leaving more things there, rather than putting them away. Take separate trips to put them away instead.

In summary, it takes time to break old habits and build new, healthier ones, but it can be done. One of the most important steps you can take is to get rid of problem cues and add new ones that will help you lead a healthier life. **You can make food and activity cues work FOR you, not against you.**

Assign home activity.

Here is what I want you to do next week. First, get rid of one problem food cue in your life. Let's make a plan for that. *(Ask the participant the questions on the work sheet and fill in the blanks).* Also, add one positive cue for being more active. *(Ask the participant the questions on the work sheet and fill in the blanks).* What problems do you think you might have in trying to make these changes? How will you deal with them?

As always, keep track of your weight, eating and activity and do your best to reach your goals (specify goals on cover of Keeping Track books).

Finally, answer these questions before you come in to the next meeting ("Did you follow your plan?" and so on). We'll talk about how you did when you come in next week.

Any questions?

Session 9: Problem Solving

Objectives:

In this session, the participant will:

- Learn the five steps to problem solving.
- Practice the steps using a problem the participant is experiencing now with eating less fat/calories or being more active.

To Do Before the Session

Have materials ready:

- Keeping Track book.
- Pages for participant notebook.

Weigh the participant.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Review Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity?

Graph physical activity.

Were you able to get rid of the problem food cue and add the positive cue for being more active? What problems did you have? What could you do differently next week?

Were you able to make the active lifestyle choices you had planned? Keep track of calories and stay under your calorie goal and/or follow the meal plan (*if applicable*)?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Introduce the upcoming sessions and the problem solving process.

In the first eight sessions of the Lifestyle Balance program, you learned *how* to eat healthy and be more active. Healthy eating and being active will help you lose weight and be healthier in general. We also hope it will reduce your chance of developing diabetes.

But healthy eating and being more active means changing your habits, and making the changes a permanent part of your lifestyle. Many things can get in the way of changing habits. That's what we'll focus on in the next several sessions. We will discuss:

- Negative thoughts,
- Slips and your reactions to slips (a slip is when you don't follow your eating or activity plan),
- Stress, and
- What people say and do (or "social cues").

All of these things can get in the way of healthy eating and being more active.

What are some examples of things that get in the way for you?

Name several problems that the participant has already discussed at earlier meetings, if possible. E.g., You wanted to go out for exercise, but it was too cold. You wanted to eat less fat, but your children wanted you to buy potato chips.

It's inevitable that problems like these will come up.

But problems can be solved. Today we're going to talk about the *process* of problem solving. This is the process that you and I will be working on together throughout the study.

Explain the five steps to problem solving.

In general, there are five steps to solving problems.

1. The first step is to **describe the problem in detail. Be specific.**

For example, instead of defining the problem as "I eat more fat than I should," be specific about the kinds of foods you eat that are high in fat--maybe high-fat desserts or red meats. Be specific about when you eat them, and describe these situations in detail. For example, you may eat high-fat desserts when you go to your mother's house and she offers them to you.

Also, **look at what led up to the problem.** Many problems involve a chain of actions: one action leads to another and then another and eventually this leads to inactivity or overeating. This is called an "**action (or behavior) chain.**"

Try to see the steps (or "links") in the action chain, including:

- **Things around you that cue (or prompt) you to eat or to be inactive.**
We've talked about food and activity cues before. Examples are a bakery near where you work, television watching, or a carton of ice cream in your freezer.

- **People in your life who don't support your efforts** to lose weight and be more active. Examples are a co-worker who offers you doughnuts every morning, children who insist that you deep-fry chicken rather than baking it, or a spouse who wants you to watch TV in the evening rather than exercise.
- **Thoughts or feelings that get in your way.** Examples are defeating thoughts like, "I'll never be disciplined enough to exercise every night." Or feelings of boredom, stress, loneliness, or anger that lead to overeating.

Here is an example of an action chain *[refer to the diagram]*:

Sarah is a busy woman with a job and a family. Yesterday she was extremely busy at work and she **didn't eat lunch** because she didn't have time to go out. In the afternoon, her **boss was very critical** and demanding, and **Sarah felt stressed and anxious**. At the end of the day, Sarah **came home tired, upset, and hungry**. She **went right to the kitchen**. She immediately **saw a package of cookies on the kitchen counter**, and before she knew it, she **ate a fair number of the cookies**.

It may seem complicated to look at a problem in this much detail. But actually, it makes problem solving much, much simpler.

- You see that the real problem may not be the last step (eating the cookies) but rather all of **the things that led up to it** (like not eating lunch and soon).
 - Uncovering the action chain will help you to **find the "weakest links" in the chain to break**. There's a saying that a chain is only as strong as its weakest link. By naming all of the links in the chain, you will be able to find the weakest ones, the places where you can make a change most easily.
2. Step 2 is to **brainstorm your options**. What are all of the possible solutions to the problem? "Brainstorming" means to create a storm of ideas in your brain. Let the ideas pour out, no matter how crazy they may seem. Anything goes. The more ideas the better. And it's actually helpful to include some crazy, extreme ideas because it helps open your mind and stir up your creative juices.

By brainstorming, **you'll see that you aren't at all powerless to change your situation**. You have many options. Here are some possible ones for Sarah *[refer to work sheet]*.

3. Third, **pick an option to try**. Weigh the pros and cons of each option, and choose one (or it might be a combination of several) that is **very likely to work** and that **you can do**. In other words, be realistic. You should be confident that you will succeed.

It's also helpful to try to **break as many links as you can, as early as you can** in the chain.

For example, it will be much easier for Sarah to control her eating in the evening if she eats some lunch and doesn't arrive home hungry. It will be easier for Sarah to avoid eating too many cookies if she doesn't buy the cookies in the first place. Another reason to try to break an action chain as early as possible is that **you will have more links to work with**.

If eating lunch doesn't help Sarah and she still arrives home tired, upset, and hungry, she can still choose low-calorie snacks like fruit when she gets home.

Let's say that Sarah chooses the option of packing a quick bag lunch.

4. Fourth, **make a positive action plan**. This is where you spell out exactly:

- What you will do,
- When you will do it, and
- What you need to do first.
- Also, make a plan for any roadblocks that might come up,
- And build in steps that will make success more likely. For example:
Will it help you to involve someone else?

Can you do anything to make it more fun and enjoyable?

Will it help if you:

Write your plan down and post it on your refrigerator or calendar?

Tell your plan to someone else, so you're committed to following it?

Join an exercise class or club so you're more committed?

Make a date with someone to exercise?

Sometimes if you build in a step to get yourself over the first "hump," then everything begins to snowball and the rest is much easier. For example, here is Sarah's action plan *[review work sheet]*.

5. The fifth step of problem-solving is to **try it and see how it goes**. Did it work? If not, what went wrong? Use what you have learned to problem solve again and make a new action plan. Remember, **problem solving is a process. Don't give up**. It often takes many tries to find a solution.

Review another example if you think it would be helpful. Use one that is tailored to the individual (for instance, an example of the food preferences of the family getting in the way of the participant's goals).

Now let's apply this process to you.

Have the participant practice the steps using a problem he or she is experiencing now.

For next week, I want you to work on solving a particular problem. Think of a problem that you're having now with eating less fat/calories or being more active.

Complete the **Lifestyle Balance Problem Solver** work sheet with the participant.

For next week:

- Keep track of your weight, eating, and activity.
- Follow your action plan. And answer the questions on the work sheet.

Session 10:

Four Keys to Healthy Eating Out

Objectives:

In this session, the participant will:

- Learn four basic principles for healthy eating out: **planning ahead, assertion, stimulus control, and healthy food choices.**
- Identify specific examples of how to apply these principles at the type of restaurant the participant frequents.
- Practice making a meal selection from an appropriate menu.
- Practice out loud how to ask for a menu substitution.

To Do Before the Session:

- If possible, have the participant bring in menus from the restaurants he or she frequents.
- Get materials ready:
- Sample menus from local restaurants.
- Keeping Track book.
- Pages for participant notebook.
- Optional handouts that are appropriate for the participant (for example, booklets on the nutrient content of fast foods).

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity? Try your action plan? What did you learn from the problem solving process?

Graph physical activity.

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Introduce the four keys to healthy eating out.

Today we're going to talk about eating out. **What kinds of places do you eat out at?**

Tailor the rest of the session to one or two of the places where the participant eats out most often. If the participant doesn't name several places or is not specific enough, prompt for a few of the following

examples: fast-food restaurants, other restaurants, church or community centers, cafeterias, friend's homes, snack bars or vending machines, in an airplane.

Do you find it difficult to stay under your fat gram goal when you eat out at these places?
What is difficult for you?

There are four basic keys to healthy eating out. *[First, indicate each of the major headings on the work sheet, as scripted below. Later you will come back to the specific points under each heading.]*

1. First, **plan ahead.** Having a plan will help you to anticipate difficult situations and handle them more easily. You won't run into so many surprises.
2. Second, **ask for what you want.** Be firm and friendly. We'll talk in a minute about how to do this so you won't offend anyone.
3. Third, **take charge of what's around you.** Take steps to make what's around you **support** you in your efforts to eat healthy. Get rid of the things that get in the way, if you can.
4. And finally, **choose foods carefully.**

Help the participant identify specific examples of how to apply the four principles.

Let's use **one of the places where you eat out as an example.**

What are some ways you can **plan ahead** for eating out at?

Follow along on the work sheet as you **discuss each of the four keys to healthy eating out as they apply to that type of restaurant.** Use some of the examples given below, but don't try to be exhaustive. Rather, choose those examples that relate to the specific difficulties faced by the participant. You may want to jot down on the work sheet a few strategies that are particularly relevant.

When you review **how to ask for what you want**, use the following script:

Many people find it hard at first to ask a waiter or waitress for something special. With practice, it gets easier. Here are some tips:

- **Begin with "I", not "You."**

"I would like," "I need," "I will have." Using "I" statements shows that you take responsibility for your own feelings and desires. "I would like my chicken broiled with lemon juice instead of gravy," or "I would like tossed salad instead of coleslaw, please."

"You should have," "you said," "you don't understand." Using "you" often puts others on the defensive. "You didn't put the salad dressing on the side!" Better: "I asked to have the salad dressing on the side, please."

- **Use a firm and friendly tone of voice that can be heard.**
- **Look the person in the eye.**
Eye contact says a lot. Avoiding eye contact often means you don't believe what you are saying.
- **Repeat your needs until you are heard. Keep your voice calm.**
Sometimes it may take several tries before you are understood. If you need to repeat yourself, keep your voice low but firm. A loud voice can be threatening to others.
Wishy-washy "Oh, well. I guess they couldn't broil the fish."
Threatening "You said you would broil my fish!"
Firm & friendly "This looks very nice. But I asked for my fish to be broiled, not fried. Would you have some broiled for me, please?"

When you review the fourth principle, **choose foods carefully**, have the participant:

- **Practice making a meal selection from an appropriate local menu.**
- **Practice out loud how they would ask for a menu substitution.**

Refer to menus from local restaurants and the "What's on the menu?" and "Fast food can be lower in fat" handouts for examples. It's important to role play aloud at this point to give the participant practice actually choosing words that are comfortable for him or her. At some point you may want to go to a restaurant with the participant and by ordering first, you can model how to make healthy meal selections and ask for menu substitutions. Participants may also need encouragement to ask family members to support them when they are at a restaurant, for example, to ask a spouse to say, "I'm glad you ordered milk for your coffee," instead of, "Are you sure you don't want cream?"

At fast-food restaurants

1. Plan ahead.

- Pick a restaurant carefully. Most fast-food restaurants now serve some low-fat foods, such as grilled chicken and salads with low-fat dressing.
- Plan what you will order without looking up at the menu. Menus can tempt you to order what you don't want.

2. Ask for what you want. Be firm and friendly.

- For example, "May I have my coffee with a little low-fat milk rather than cream, please?"
"Please leave the mayo off my burger."
- Ask how much is usually served. For example, "How many ounces is the hamburger, please?"

3. Take charge of what's around you.

- Be the first in your group to order. You won't be tempted by what or how much others order and they may follow your good example.

4. **Choose foods carefully.**

- Try grilled chicken sandwiches without special sauces or a salad with low-calorie dressing.
- Stay away from French fries. If you must have them, order a regular size (not a double) and Don't finish them all.
- If you must have a hamburger, order a regular size, without cheese, not a double or a cheeseburger.

At other restaurants (not fast-food)

1. **Plan ahead.**

- Pick the restaurant carefully. Go to one with low-fat choices. Call ahead to see what is on the menu. Stay away from "all you can eat" buffets, brunches, and happy hours.
- Eat less calories and fat during other meals that day or for a few days in advance.
- Have a little something to eat before you go to the restaurant so you're not too hungry when you get there. Eat fruit, some low-fat crackers, or drink water before you go out.
- Plan what to order without looking at the menu. Looking at the menu can tempt you to order more than you want.
- Don't drink alcohol before the meal. It may make it harder for you to follow your good intentions. Try tomato juice, club soda, or mineral water, instead.

2. **Ask for what you want. Be firm and friendly. Remember, you are paying for the meal. You have the right to ask for special services. And most restaurants want to make you happy.**

Ask for the foods you want:

- Ask for food substitutions. For example, catsup or mustard instead of mayonnaise on a sandwich. A tossed salad instead of coleslaw. Baked potato instead of French fries.
- Can foods be prepared in a different way? For example, ask that the fish be broiled and seasoned with lemon juice, not butter; ask that butter, margarine, and sauces be left off the vegetables.
- Don't be afraid to ask for foods that aren't on the menu. Many restaurants will prepare grilled meats, fish, and chicken without added fat or sauces, fresh fruit salads, and steamed vegetable platters with rice, even if they're not on the menu. Or look for foods on a different part of the menu (for example, if fresh fruit is on the breakfast menu, it may well be available as a dessert for dinner).

Ask for the amounts you want:

- Ask how much is usually served. For example, "How many ounces is the hamburger, please?"
- Ask for salad dressings, gravy, sauces, or spreads "on the side." For example, ask for dry toast with margarine on the side. Then use only a small amount. Or order salad dressing on the side, then limit the amount you use. (One idea is to dip your fork into the dressing before each bite.)
- Ask for less cheese or no cheese.

- Split a main dish or dessert with someone. Or order an appetizer as a main dish.
- Order a smaller size (appetizer, senior citizen's or children's portion, cup of soup).
- Before or after the meal, have the amount you don't want to eat put in a container or "doggie bag" to take home.

3. Take charge of what's around you.

- Be the first to order. You won't be tempted by what others order, and they may follow your good example.
- Keep foods off the table that you don't want to eat.
 - a. When a waiter or waitress brings rolls, chips, or other complimentary foods, say "No, thank you," and hand the food back right away.
 - b. When you order something, ask that half of it be put in a doggie bag **before** it's brought to the table. Then have it brought to you with the check.
- Ask that your plate be removed as soon as you are finished. You won't be tempted to eat more than you want while others finish their meals.
- Remove table tents from the table that advertise high-fat/calorie foods such as desserts.

4. Choose foods carefully.

- You can tell a lot from the words on a menu. Watch out for these high-fat words; look for these low-fat words, instead. [Refer to handout.]
- Watch out for sauces on meats, vegetables, and so on. Ask that these foods be served without the sauce.
- Think about how much food you really need. Do you need an appetizer? Bread? Make some compromises. "I'd rather have dessert so I'll skip the appetizer."
- Trim visible fat off meat.
- Take skin off chicken.

At another person's home or community center/potluck dinners

1. Plan ahead.

- Bring something from home for yourself and others. Examples: fruit salad, vegetable salad with low-calorie dressing.
- Talk to the host or hostess before you go, if you are comfortable doing so (particularly if you eat at their home often). Ask for their support in your efforts to lose weight.
- Eat a little something before you go, so you aren't too hungry when you arrive.

2. Ask for what you want. Be firm and friendly.

- Say "No, thank you. That looks lovely, though," when offered a food you'd rather not eat.

3. Take charge of what's around you.

- At buffets or cocktail parties, stay away from the buffet or appetizer table. Choose a small plate, and after serving yourself, sit at a table far away.

4. **Choose foods carefully.**

- Take only a small amount of high-fat/calorie foods, just enough to taste.
- Look at everything on the buffet before serving yourself. Then choose only 3 or 4 of your favorite foods, instead of trying a little of everything.

Airplanes

1. **Plan ahead.**

- Order a special menu ahead. Call 24 hours before departure. Many airlines have low-fat and vegetarian menus available.

2. **Take charge of what's around you.**

- Say "No, thank you," smile, and hand the peanuts right back to the flight attendant.

Banquets, Conferences

1. **Plan ahead.**

- Ask what is on the menu. Is anything prepared without fat?
- Order a special menu ahead. Even if the choices are limited, many caterers will prepare a steamed vegetable plate with rice and fruit salad upon request.

Assign home activity.

Describe a problem you have when you eat out. *[Record on the work sheet.]* Choose one of the four keys to healthy eating out that is likely to help you solve the problem and that you can do. Make a positive action plan. *[Complete the work sheet with the participant.]*

For next week:

- **Keep track** of your weight, eating and activity.
- **Try your action plan.** And before you come to the next session, answer the two questions on the bottom of the work sheet (Did it work? If not, what went wrong?).
- For participants who eat out often, ask the participant to collect menus for restaurants the participant frequents and bring them in to the next session.

Any questions?

Session 11: Talk Back to Negative Thoughts

Objectives:

In this session, the participant will:

- Recognize that everyone has negative thoughts and identify examples of them.
- Learn how to stop negative thoughts and talk back to them with positive ones.
- Practice stopping negative thoughts and talking back to them with positive ones.

To Do Before the Session:

Get materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Optional handouts that are appropriate for the participant (for example, a Stop! Sign prop to hold up when you hear the participant expressing a negative thought).

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity? Try your action plan? What did you learn last week about healthy eating out?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Graph physical activity.

If the participant has brought in restaurant menus, help the participant practice ordering from the menus.

Help the participant identify examples of negative thoughts.

Today we're going to talk about stopping negative thoughts.

Everyone has negative thoughts at times. These negative thoughts can lead you to overeat or be inactive. Then afterwards you may feel even worse about yourself. A vicious cycle of self-defeat can result.

For example, suppose you came home after a hard day at work. You think to yourself, "I'm tired of working so hard. I'm sick of being in this study. I can never eat what I want." This negative thought might lead you to eat some potato chips. And then you think, "I did it again. I'll never lose weight." Next, you're discouraged and go on to eat more of them.

Sometimes we aren't aware we are having negative thoughts. Negative thinking becomes such a habit for most of us that we tend to believe and act on our negative thoughts without even hearing them.

The goal of this session is to help you hear your negative thoughts and teach you to talk back to them.

Here are some common examples of negative thoughts.

Review each category and the example(s) on the work sheet, then ask a question or two to get the participant thinking about his or her own experience with negative thoughts.

1. Good or Bad Thoughts.

These thoughts divide the world into:

- Good and bad foods;
- Seeing yourself as a success or failure;
- Being on or off the program.

Sometimes this is called "all or nothing" or "light bulb" thinking (either on or off) with nothing in between.

Example: "Look at what I did. I ate that cake. I'll never be able to succeed."

- Do you have some foods you consider "good," and some foods you consider "bad?"
- What happens when you eat a little of what you consider to be a "bad" food?
- Can you think of some problems with considering a food "bad?"

2. **Excuses (or Rationalizations)**

These thoughts **blame something or someone else for our problems**. We act as if they have so much power that we have no choice but to overeat or be inactive.

We don't mean to go off the program, but we "can't help it."

Example: "I don't have the will power."
"I have to buy these cookies just in case company drops in."

- Can you think of a time when you bought some high-fat/calorie food "for someone else"? Did they really need the food, or do you think you used them as an excuse to buy the food for yourself?

3. **Should Thoughts.**

These thoughts **expect perfection**. Of course, no one is perfect, so SHOULD thoughts are a **set-up for disappointment**. They also **lead to anger and resentment** because "should" assumes that someone is standing over us, forcing us to do what we don't want to do.

Example: "I should have eaten less of that dessert."

- What kind of things do you think you "should" or "should not" do to lose weight and be more active?
- What do you expect yourself to do perfectly (for example, self-monitoring)? What happens when you expect perfection of yourself? How do you feel? How does it affect your future decisions and choices?

4. **Not As Good As Thoughts.**

These thoughts **compare us to someone else** and then **blame ourselves for not measuring up**.

Example: "Mary lost two pounds this week, and I only lose one."

- Do you compare yourself to someone else? Who?
- How does comparing yourself to that person affect you? How does it make you feel? How does it affect your decisions and choices about eating and being active?

5. **Give Up Thoughts.**

These thoughts **defeat us**. They **often follow the other kinds of negative thoughts**.

Example: "This program is too hard. I might as well give up."

- Do you ever want something good to eat and think, "I'm sick of this Lifestyle Balance program"?

Explain how to talk back to a negative thought.

Once you are aware of a negative thought, you can "talk back to it." Here's how:

1. First, **catch yourself** having the negative thought. Ask yourself, "Is this thought moving me forward or bringing me down?" As soon as you're aware of a negative thought, say to yourself, **"I'm doing it to myself."**
2. Then **imagine shouting "STOP!" to yourself.** Picture a **huge, red stop sign.** *[You may want to hold up the STOP! sign prop at this point.]* The stop sign is so big that it takes up all the room in your mind. This should startle you and get rid of the negative thought.
3. **Talk back with a positive thought.** No matter how effectively you've stopped a negative thought, it will probably return again in a similar situation because it has become a habit for you. So it's important to **begin to build a new habit: positive thinking.** After you stop a negative thought, talk back to it with a positive one.

Review the categories and the examples on the work sheet, making the following points.

- **Good or Bad:** Talk back with **Work Toward Balance.**
Don't expect perfection of yourself, but don't indulge yourself either. Work toward an **overall balance.**
- **Excuses:** Talk back with **It's Worth a Try.**
Instead of looking for something or someone else to blame, why not give yourself a chance? Try something. You just might succeed.
- **Should:** Talk back with **It's My Choice.**
You are in charge of your eating and activity. No one else is responsible for your choices or standing over you with unrealistic expectations.
- **Not As Good As:** Talk back with **Everyone's Different.**
- **Give Up:** Talk back with **One Step at a Time.**
Problem solving is a process. It takes time to make life-long changes. Learn from what doesn't work and try another option. Learning is always a success.

Now let's **practice** stopping negative thoughts and talking back with positive thoughts.

Look back over the kinds of negative thoughts we've discussed. What kind are most familiar to you? For example, do you tend to make excuses or are you more likely to compare yourself to someone else? What are some examples?

Write examples of negative thoughts on the work sheet. If the participant doesn't name examples, use several from the previous pages.

Now let's take them one at a time. First, say the negative thought out loud. Then say "Stop!" And then talk back to it out loud with a positive thought.

Use the remaining time in the session to actually role-play this with the participant. Use a stop sign prop if you find it helpful. Record the positive thoughts on the work sheet.

This session may be an appropriate time to review with participants the work sheet "Remember Your Purpose" (Session 1) on which they recorded their personal reasons for joining the study and so on. Details from this work sheet may provide images and words for the participant to use in talking back to negative thoughts with positive ones. Any imagery that is significant to the participant may help make the process of "talking back" more meaningful and fun; for example, a participant might find it enjoyable to imagine a devil on one shoulder and an angel on the other, and to see the task of positive thinking as, "letting the angel talk."

Assign home activity.

For next week:

- Keep track of your eating and activity.
- Catch yourself thinking negative thoughts. Write them in your Keeping Track books.
- Practice stopping them and talking back to them with positive thoughts.

Next week we'll talk about how you did.

Any questions?

During this session, some participants may raise problems outside the expertise of the Lifestyle Coach, such as a significant clinical depression, anxiety, or a clinical eating disorder.

Session 12: The Slippery Slope of Lifestyle Change

Objectives:

In this session, the participant will:

- Review the participant's progress since Session 7 or 8 ("Tip the Calorie Balance").
- Identify some things that cause the participant to slip from healthy eating or being active.
- Discuss what to do after a slip to "get back on your feet again."

To Do Before the Session

Review the participant's progress. Note any plans that were made to improve weight loss and activity level, which strategies were used, and which were successful or unsuccessful. If the participant is not currently at goal for weight loss and/or activity, refer to the Tool Box for ideas of additional strategies required or optional for particular problems.

If you have copies of some of the participant's past Keeping Track records, review them as well. Note some of the positive changes the participant has made.

Make sure the participant's How Am I Doing? graphs for weight and activity are up to date.

Have materials ready:

- Keeping Track book.
- Pages for the participant notebook.
- Meal plans appropriate for the participant's calorie goal. Tailor to the participant's food preferences as much as possible before the session.

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity? What negative thoughts did you catch yourself thinking? Were you able to stop them and talk back with positive thoughts?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Graph physical activity.

Review the participant's progress since Session 7 or 8, and if not at goal, develop an action plan to improve progress in reaching weight loss and activity goals.

Today we're going to talk about what are called "slips," or times when you don't follow your plans for healthy eating or being active.

Let's use skiing as an example. Everyone who learns to ski knows that they will "slip" and fall down. It's a natural part of learning to ski. What a skiing instructor does is to help beginning skiers anticipate when they might fall down and show them how to get up again. That's what we'll do today--talk about when you might "slip" from your eating and activity plans, and how you can get back on track again after you slip.

Note: Throughout this session, try to use analogies in addition to skiing that are meaningful to the participant. (For example, one analogy is how we handle fires. First, we try to identify high-risk situations in which fires are likely to occur. Second, we try to take steps to avoid these situations if we can. Third, in case a fire does occur, we plan ahead for a way to put out the fire and/or escape.

We make a plan that is as simple and easy to remember as possible so that we are more likely to follow it while under stress.) You will also want to use a meaningful analogy for how the participant has developed other skills by making mistakes and learning from them, such as learning to drive a car, bake a cake, and so on.

Before we talk about slips, we'll take some time to review your progress

- **What are some of the major changes you've made to be more active?** Include both what you do to reach your goal (that is, those activities you record) and what you do to be more active in general **What changes have you made to eat less fat (and fewer calories)?** Briefly record on the work sheet some of the changes made by the participant. Praise and encourage the maintenance of these changes.

Have you reached your weight goal? Your activity goal?

Refer to the How Am I Doing? graphs for weight and activity, and check yes or no on the worksheet.

If the participant is **at goal** for weight loss and activity, praise the progress made.

If the participant is **not at goal** for weight loss or activity, praise whatever progress has been made. Encourage the participant to improve, and develop a related plan using the work sheet. **Follow the guidelines in the Tool Box as to which strategies are required to address particular problems identified.** For example, some participants may need to be given meal plans at a lower calorie level.

Define slips.

Now let's move on to the topic for today, "**slips.**"

Slips are times when you don't follow your plans for healthy eating or being active.

Slips are:

- **A normal part of lifestyle change.** Just like falling down is a normal part of skiing. If you are going to ski, you are going to fall. All skiers will fall. And everyone who sets out to lose weight and be more active will have slips.
- **To be expected.** If you haven't already had some slips, you most certainly will have them in the future. Slips are **inevitable**.

Does this sound discouraging? Well, it doesn't have to be. Because **slips don't hurt your progress. What hurts your progress is the way you react to slips.** So today we'll talk about the best way to react to slips when they happen.

Identify some things that cause the participant to slip from healthy eating or being active.

Different people have different things that cause them to slip. For example, **moods or feelings** cause many people to slip from healthy eating.

Some of us tend to overeat when we're **happy**. Imagine that:

Your **family is celebrating**. Maybe it's a holiday, a birthday, or a vacation. There is plenty of everyone's favorite foods, from appetizers to desserts. And for years, your family's custom has been to "take it easy," have fun and just relax during these times. **What would this situation be like for you? Would you tend to slip in this kind of situation?**

Some of us are more vulnerable to overeating when we're **bored**. Imagine that:

You're **at home alone, watching a favorite TV program**. You're feeling okay, pretty relaxed, but a little bored. A commercial comes on at the end of the program, and you find yourself wandering into the kitchen. **What would this be like for you?**

Other people overeat when **upset**. Imagine that:

You are settling down for a relaxing evening at home. Someone in your family starts to talk about something that's been part of an **ongoing argument** between the two of you. You both get angry and he or she stomps out of the house, slamming the door. You head for the kitchen. **What would this situation be like for you?**

Or here's another example:

You're **behind on a project at work**. The boss has been looking in on you every 10 minutes and glaring at you impatiently. You feel pressured and very tense. You go get yourself a cup of coffee and see a delicious snack that someone brought in that morning. **What would this be like for you?**

Which is the *most* difficult for you in terms of slipping from healthy eating: feeling happy, bored, or upset? *[Record on the work sheet.]* **Are there other things that cause you to slip from healthy eating?**

Give the participant time to name a few examples. Record on the work sheet.

What things cause you to slip from being active?

Have the participant name several examples, such as vacations, holidays, feelings or moods, cold or hot weather.

The situations that lead to slips differ from person to person. For example, you may tend to eat when you're bored, whereas someone else may get involved in a hobby. Or when you are at a party, you may be so busy talking and laughing that you forget to eat, whereas someone else may find the goodies are just too tempting. **What causes you to slip is learned. It is a habit.**

The way you react to slips is also a habit. You can learn a new way to react to slips that will get you back on your feet again.

Discuss what to do after a slip to get back on your feet again.

First, **remember two things:**

- **Slips are normal and to be expected.** 99.99% of all people who are on their way to losing weight and being more active have slips. But a slip doesn't need to lead to giving up completely. Slips can and should be useful learning experiences.
- **No one time of overeating or not being active, no matter how extreme, will ruin everything.** You won't gain more than a few pounds of weight even after the biggest eating binge imaginable--unless you stay off track and keep overeating time and time again. **The slip is not the problem. The problem occurs if you don't get back on your feet again and keep going toward your goals.**

So after you have a slip:

1. **Talk back to negative thoughts with positive thoughts.**

The negative thoughts that come after a slip can be your worst enemy. They can lead to feeling discouraged, guilty and angry and undermine your ability to handle the slip effectively. Talk back to the negative thoughts with positive ones. "I am not a failure because I have slipped. I can get back on my feet again."

2. Next, **ask yourself what happened.**

Use the opportunity to look closely at the situation and ask yourself what happened. Was it a special occasion? If so, is it likely to happen again soon? Did you overeat because you were lonely, bored, or depressed? Did you eat because of social pressure? Did you skip activity because you were too busy with other things, or because of work and family pressures? Use these questions to review the situation and think about it objectively.

Learn from the slip.

Then you can plan a strategy for handling the situation better next time. **Can you avoid this situation in the future** (for example, by not sitting near the food or by not wheeling past the candy machine)? If you can't avoid it, **can you manage it in a better way** (for example, by making sure you have low-calorie foods available at home)?

3. **Regain control the very next time you can.**

Do **not** tell yourself, "Well, I blew it for the day," and wait until the next day to start following your eating plan. **Make your very next meal a healthy one. Get back on schedule with your activity plan right away.** You will not have set yourself back very much if you follow this suggestion.

4. **Talk to someone supportive.** ("Talk it through, don't eat it through.")

Call your lifestyle coach or someone else on staff. Call another participant or another friend. Discuss your new strategy for handling slips. Commit yourself to renewed effort.

5. Finally, **focus on all of the positive changes you have made** and realize that you can get back on track. The same person who "blew it" today is the same person who has been successful during many previous weeks. Slips do not reveal the "real you" (hopeless, lacking willpower, etc.). They are simply another occasion of behavior. **Remember, you are making life-long changes. Slips are just one part of the process.**

Assign home activity.

Describe one thing that has caused you to slip from healthy eating.

Could you **avoid it** in the future? If so, how? *[Record on the work sheet.]*

If not, make a plan for **how to get back on your feet** the next time you slip. *[Record.]*

Describe one thing that has caused you to slip from being active.

Could you **avoid it** in the future? If so, how? *[Record on the work sheet.]*

If not, make a plan for **how to get back on your feet** the next time you slip. *[Record.]*

For next week: a) Keep track of your eating and activity. b) Try your two action plans.

c) Answer the questions on the work sheet.

Any questions?

Session 13: Jump Start Your Activity Plan

Objectives:

In this session, the participant will:

- Discuss ways to add interest and variety to the participant's activity plans.
- Learn the definition of "aerobic fitness."
- Learn the F.I.T.T. Principles (frequency, intensity, time, and type of activity) as related to heart (aerobic) fitness.

To Do Before the Session:

Have materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Optional handouts that are appropriate for the participant (for example, on various barriers to physical activity).

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity?

Did you try your two action plans to get back on your feet after slipping? How did it go?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Graph physical activity.

Discuss ways to add interest and variety to the participant's activity routine.

So far in the Lifestyle Balance program, our focus in terms of physical activity has been on increasing the amount of time you are active. We've moved gradually from 30minutes per week to 2 ½ hours per week of new physical activity. By this time in the program, many participants find that their activity routine has become a little stale and boring. **Boredom is a problem because it may cause you to slip back into old habits of not being active.** So it's important to be aware of

any boredom you're feeling about your activity plan, and do something to keep it fresh and interesting.

That's what we'll talk about today--**ways to "jump start" your activity routine** (or give it new energy when it's becoming a little too "routine").

First, **add variety**.

- **Do something new and different** now and then. Don't expect yourself to do the same activity, day in and day out, every season of the year, any more than you would expect yourself to eat the same food, day in and day out, all year long. Remember, you are making life-long changes, and being active is something you will be doing for the rest of your life. So build in some variety. For example, if you usually do aerobic conditioning during the week, strength (resistance) training on the weekend.

Can you think of some ways to vary what you do for activity?

Record on the work sheet. Include lifestyle activity but be sure the participant understands to self-monitor only the physical activities that are similar (or higher in) intensity (refer to Manual of Operations).

If the participant expresses interest in learning more about a particular activity, such as strength(resistance) training, consider making an appointment for the participant to meet with the exercise specialist on staff for instruction.

Do the same activity in a new place. For example:

- Wheel on a different path through the park.
- Wheel in a different neighborhood after work.

What are some ways you can vary where you do your activity? (*Record.*)

Be active as a way to be social.

- Instead of going out for a cup of coffee, go out for a "wheel and talk" with a friend or family member.
- Plan a weekend hike with a group of friends.
- Go wheeling with a club.
- Join a basketball team.
- Sign up with a group of friends for a wheel for charity.

What are some activities you could do with a friend, family member, or group as a way to socialize? (*Record.*)

It also helps if you **make being active fun**.

- Some people enjoy listening to a radio, music tapes or books on tape while they exercise
- Plan tours of cities when you travel.

What would be fun for you? (*Record.*)

Another way to prevent boredom is to **challenge yourself**.

- Prepare yourself for a race.
- Set up a friendly competition with a friend (whoever wheels the most miles before a certain date gets taken out to lunch by the other).

What would make activity more challenging for you? (*Record.*)

Have you been bored at times with your activity in the past?

Have you found anything to be particularly helpful for you at those times?

If you're not bored now, please be sure to bring it up whenever you do feel bored in the future. Use me and our activity specialist as resources to help you. For example, we can talk about some community programs that might add interest to your activity routine, and so on.

Define "aerobic fitness."

One way to add something new to your activity routine is to begin to focus on **improving your "aerobic fitness."**

"Aerobic fitness" refers to **how well your heart can pump oxygen ("aer-")** through your blood to your muscles in your body.

Your heart is a muscle, too. If you exercise your heart (make it beat faster), it will become stronger over time. This is just like the muscles in your arm becoming stronger if you lift weights every day.

As your heart becomes stronger, you'll notice that it's easier for you to do things like wheeling up inclines and carrying groceries.

Explain the F.I.T.T. Principles.

Not all ways of being active will help strengthen your heart--only those that are "F.I.T.T."

This is what "F.I.T.T." stands for:

"F" stands for **frequency**, or **how often you are active**.

Aerobic fitness levels go down within 48 hours of no activity, so it's important to be active often.

- Try to be active on most days of the week (at least 3 days per week is recommended; 5 to 7 days are even better).
- To avoid soreness and injury, it's best to **increase the frequency slowly**.

"I" stands for **intensity**, or **how hard you are working while being active**.

This is usually measured by **how fast your heart beats**. We want your heart to beat faster than it usually does, so that it will become stronger, but we don't want it to beat so fast that you could injure yourself.

- The goal is to stay within what's call your "target heart rate", about 50-70 % of the maximum number of times your heart can beat in a minute for someone your age.

Here is how to **figure your target heart rate**.

Review the formula on the work sheet and calculate the participant's own target heart rate.

Have you ever taken your heart rate or pulse?

Review with the participant the steps for taking your heart rate as described on the work sheet. Use a pen or marker to mark on the participant's wrist exactly where he or she is able to find the pulse. This will help the participant find it quickly when exercising.

- Another way to get a rough idea of how hard you should be working is to **breathe fast enough that you can talk but not sing**. You should be able to have a conversation with a friend while exercising, but **if you can break into song, speed it up!**

On the other hand, **if you have trouble breathing and talking while you exercise, slow down**.

- **As you do regular physical activity over time, your heart doesn't beat as fast** as it used to. For example, you'll notice that your heart doesn't beat as fast when you wheel up an incline, and you don't get as out of breath.

This means that you are becoming more fit, that your heart is doing the same amount of work with less effort. It also means that to continue strengthening your heart, **you will need gradually to do more challenging activity to reach your target heart rate**. For example, you'll need to exercise more intensely than you used to get the same benefit in terms of aerobic fitness.

"T" stands for **time**, or **how long you are active**.

- To improve your aerobic fitness, you should **stay active continuously for at least 10 minutes**. That's why we don't ask you to record in your Keeping Track any activity that doesn't last at least 10 minutes.
- We recommend that you **slowly increase the time you are active to 20 to 60 minutes**.
- The **total number of minutes per week should at least equal your Lifestyle Balance activity goal for that week**.

The final “T” stands for **type of activity**.

- To improve your fitness, you should do “**aerobic**” activities. As we said before, these are activities that **challenge your heart**. Brisk exercise will result in aerobic activities.
- These activities **use large muscle groups** and
- **Last 10 minutes or longer**. Brief activities that don't require your heart to work harder, such as bowling, pitching a softball, or washing a window, will not improve your aerobic fitness.

Introduce another way to measure exercise intensity.

Measuring your heart rate is one way to keep track of your intensity (or how hard you are working) when you're active. But even without measuring their heart rate, most people have a good sense of how hard they're working when they're active, just by listening to their body.

Rate yourself on this scale while you're being active. How hard are you working?

Review the work sheet with the participant. For your own background information as a Lifestyle Coach, the scale is based on Borg's original Rating of Perceived Exertion (RPE) Scale which is a numerical scale from 6 to 19, with 7 corresponding to very, very light, 9 to very light, 11 to fairly light, 13 to somewhat hard, 15 to hard, 17 to very hard, and 19 to very, very hard. The original scale was designed to approximate what one would estimate the corresponding heart rate to be, by adding a zero to the end of the RPE. For example, an RPE of 13 (somewhat hard) would approximate a heart rate of 130. So if a participant calculated her upper heart rate limit to be 130, her upper RPE limit would be around 13.

Assign home activity.

For next week:

- Keep track of your weight, eating and activity.
- Do your best to reach your activity goal for the week. *[Record.]*
- Take your heart rate or pulse every time you're doing physical activity.
- Adjust how hard you are working during an activity so that you stay within your target heart rate *[specify]* or keep how hard you are working at this level *[specify]*.

Any questions?

You may want to ask the participant to invite a family member to the next session, Make Social Cues Work for You, if you and the participant think that would be helpful in planning strategies for handling social cues.

Session 14:

Make Social Cues Work for You

Objectives:

In this session, the participant will:

- Review examples of problem social cues and helpful social cues.
- Discuss ways to change problem social cues and add helpful ones.
- Review strategies for coping with social events such as parties, vacations, having visitors, and holidays.
- Make an action plan to change a problem social cue and add a helpful one.

To Do Before the Session:

Ask the participant to invite a family member to this session if you and the participant think that would be helpful in planning strategies for handling social cues.

Have materials ready:

- Keeping Track book.
- Pages for participant notebook.
- Optional handouts that are appropriate for the participant (for example, with tips for handling parties, holidays, vacations, and other social events; low-fat/calorie recipes for entertaining; helpful ideas for low-fat eating and staying active while traveling).

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity?

What was it like taking your pulse or **heart rate**? Were you able to stay within your target heart rate?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Graph physical activity.

Review the concept of food and activity “cues” and define social cues.

In an earlier session we talked about **how to “take charge of what’s around you.”** We took an imaginary video camera through your house and where you work, and we looked for problem food or activity “cues,” things that would prompt you to think about eating or to be inactive, like a TV set or a bag of cookies on a kitchen counter. We planned some ways to get rid of problem cues and add positive cues (for example, watch less TV, keep high-fat foods out of the house).

In that session we focused on the sight and smell of food or certain activities that make you think about food. Today we’re going to talk about **social cues**, or **what other people say or do that affects your eating and activity**. Again, we will plan some ways to **reduce problem social cues** and some ways to **add positive ones**.

Give examples of problem social cues and positive social cues.

Problem Social Cues

One of the most powerful **problem social cues** is:

- **The sight of other people eating problem foods or being inactive** (for example, you go to a bar where you see other people eating potato chips and watching TV). Can you think of an example in your own life? Is it difficult for you when you see someone in your family or a friend eat certain foods? (Record examples briefly on the work sheet.)
- **Being offered (or pressured to eat) problem foods or being invited to do something inactive** are also negative cues (for example, your spouse buys you candy for your birthday or a friend asks you to come over to watch football). What are some examples in your own life?
- **Being nagged** is a negative cue (for example, your spouse says, “You shouldn’t be eating that bacon. It’s too high in fat.”). Some people may think that nagging is helpful, but actually it tends to cause the behavior it’s designed to stop. Does anyone nag you about your eating or activity?
- **Hearing complaints** is a negative cue, too (for example, your daughter says, “I hate this frozen yogurt. Real ice cream is better,” or your spouse says, “You’re always outside exercising. You don’t have any time for your family any more.”).

Do you hear complaints from anyone about your eating or activity?

Now let’s compare problem social cues with **positive social cues**.

Positive social cues include:

- The **sight of other people eating healthy foods or being active** (for example, you go out to dinner with another participant who orders low-fat foods or you go to an aerobics class). Can you think of any people who are good examples for you? In what way? (Record on the work sheet.)

- **Being offered healthy foods or being invited to do something active** (for example, your mother offers you fruit salad for dessert or asks you to go for a wheel). Does anyone do this for you?
- **Being praised** (for example, your spouse says, “The oatmeal was delicious this morning, honey.”). Who praises you for your efforts and accomplishments?
- **Hearing compliments** (for example, your daughter says, “Thanks for buying frozen yogurt, Mom. It’s a lot healthier than ice cream,” or your spouse says, “You’re really committed to exercising every day. I’m proud of you.”). Does anyone compliment you?

When you respond to a social cue in the same way over and over again, you build a habit.

The cue becomes paired with the way you respond, and your response becomes more and more automatic. In an earlier session, we used the example of eating popcorn whenever you go to the movies as a food cue that over time becomes a habit for many people. It works the same way with social cues.

Let’s say that since childhood, your mother has offered you second helpings of food at the dinner table. You developed a habit of accepting her offer. Now when you return home as an adult and your mother offers you second helpings, it is hard for you to refuse.

It’s important to understand that with social cues, the **other person has also learned a habit**. So in the example we’ve just used, your mother has learned to offer you second helpings and expects that you will accept the offer. **This makes social cues even harder to change than other cues.**

Discuss ways to change problem social cues.

How can you change problem social cues?

1. As with problem food cues, one of the best things you can do is to **stay away from the cue, if you can**. For example:
 - Move to a different room if a family member eats problem foods in front of you.
 - Skip certain parties that are just too tempting for you.
 - Socialize with people by going bowling, dancing, or to the movies. Don’t go out to eat as a way to socialize.
 - Change the subject when someone starts talking about food or your weight or activity.
2. **Change the cue, if you can**. This means trying to influence the other person’s habit, if you can. For example, when someone nags, complains, eats problem foods in front of you, or pressures you to eat:
 - **Discuss the problem. Brainstorm options**. For example, “It’s hard for me when you eat ice cream in front of me. It really tempting. Is there away we could get together and have fun, but not eat ice cream?” **Be willing to compromise** to find a solution that will work for everyone.

- **Tell people about the study, your efforts to lose weight and be more active, and why this is important to you.** Many people will be willing to help if they understand that you are trying to change your eating and activity and why.
- **Ask others to praise you for your efforts and ignore your slips. This is KEY to your success.** Explain to your friends and family that this is what would be most helpful to you. In turn, be sure to thank them when they notice your efforts and overlook your slips.

(Role play this with the participant, using an example that is meaningful to him or her.)

3. If you can't stay away from the problem social cue or change it, **practice responding in a more healthy way.** Over time you will **build a new, healthier habit** and **the other person will learn a new habit, too**, because of your new response. For example:

- **Say "No" to food offers.** If you are consistent and continue to say "No," others will eventually stop offering.
- One of the most important things you can do is to **show others you know they mean well, and suggest something they can do to help you. Be specific.** Most people mean well when they nag, offer food or pressure someone to eat (for example, many people think that being a good hostess means insisting that guests have second helpings). If you recognize that they mean well and give them a specific, positive alternative, they can still feel helpful and you are more likely to reach your goals, too. For example, when a hostess offers you second helpings, say, "Thanks so much for offering. You know what I'd really enjoy is some coffee." **If you can, give them specific ideas of how to help ahead of time**, before you are confronted by a challenging situation.

Role play saying "No" to food offers, using an example that is meaningful to the participant.

Illustrate that the participant should be prepared to say "No" several times to someone who continues to offer, e.g., "Are you sure you don't want a piece of cake?"

Remember that **it takes time to break an old habit or build a new one.** Change doesn't happen overnight. And with social cues, there are at least two people involved in making a change: yourself and someone else. **Don't expect other people to adjust instantly** to a new way of relating, any more than you expect yourself to change instantly.

Discuss ways to add positive social cues.

Not all social cues are problems. You can use social cues to *help* you eat healthier and be more active. For example:

- **Spend time with people who are active and make healthy food choices.** For example, at parties stand next to people who spend most of their time talking and dancing instead of eating.
- **Put yourself in places where people are active.** For example, join an exercise club or sports league. Come to the study activity sessions.

- **Set up a regular “date” with others to be active.** You will be more likely to be active because you won’t want to disappoint them by cancelling.
- **Ask your friends to call you to remind you to be active or to set up dates to be active.**
- **Bring a low-fat/calorie food to share.** For example, bring a fruit salad to a potluck dinner.
- **Be the first to order when you eat out at a restaurant** and order healthy foods. This is much easier than waiting until after others order high-fat foods and then trying to make a healthier choice. In addition, you will provide a positive social cue for other people.
- **Be social by doing something active.** For example, exercise and talk. Go out dancing instead of going out to dinner. Start a family tradition of going for exercise after dinner instead of watching TV.

An important way to change negative social cues and add positive ones is to **ask people who want to support you for help.**

What people in your life want to support you? *[Record a few names.]*

What could they do to help you? Here are some ideas. Would any of these be helpful to you?

Review the ideas on the work sheet. Check a few that the participant thinks would be helpful.

Add other ideas at the bottom of the chart. Some participants may want to copy the work sheet to give to a supportive friend or family member.

Discuss ways to handle social events such as parties, having visitors, or holidays.

Social cues are especially powerful at social events such as parties, holidays, vacations, and when you have guests in your home or are a guest in someone else’s home. These events:

- **Upset our routine** (for example, you usually exercise after dinner, so how do you fit exercising in on a day when you’re going to a party after dinner?),
- **Challenge us with unique food and social cues** (for example, your family serves appetizers whenever there are guests in the house but not at other times; you go on vacation to a place you’ve never been before and you’re not familiar with any of the restaurants),
- **May involve habits that have developed over many years and so can be very powerful** (for example, for the past 30 years on Thanksgiving, your family has watched the parade on TV and had pumpkin pie with whipped cream for dessert).

What are some social events that are difficult for you?

Get an idea of the kind of social events the participant attends. If it is near a holiday or vacation, you may want to focus during the remainder of the session on brainstorming options and making an action plan for that specific event. Optional participant handouts (see Appendix) are available that provide guidelines for holidays, parties, vacations, and so on.

To handle social events well, try to anticipate the problems that will occur. What exactly might be difficult for you? Then brainstorm your options ahead of time. Here are some ideas: *[review the examples on the work sheet]*:

- **Plan ahead.**
- **Stay away from problem cues when you can.**
- **Change problem cues.**
- **Respond to problem cues in a more healthy way.**
- **Add helpful social cues.**

Stay positive. Think of every social event as an opportunity to learn what works well for you and what doesn't. Remember, you are building healthy habits for a lifetime.

For participants that entertain, you may want to distribute some low-fat/calorie ideas and/or recipes (for example, recipes for low-fat dips and a list of low-fat crackers). Participants who travel often may appreciate the optional handout on helpful ideas for low-fat eating and staying active while traveling.

Assign home activity.

With the participant, develop and record on the work sheet two action plans to:

- Change a problem social cue.
- Add a helpful social cue.

If it is near a holiday, vacation, or particular social event, include an action plan for that event.

Assign home activity.

This week:

- Keep track of your weight, eating and activity.
- Try your two action plans for making social cues work for you.

And before the next session, answer the questions (Did it work? If not, what went wrong?) for both action plans

Session 15: You Can Manage Stress

Objectives:

In this session, the participant will:

- Discuss how to prevent stress and cope with unavoidable stress.
- Discuss how study participation can be a source of stress and how to manage that stress.

To Do Before the Session:

Have materials ready:

- Keeping Track book.
- Pages for participant notebook.

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity?

Were you able to follow your action plans (change the problem social cue and add the helpful one)?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant.

Graph physical activity.

Define stress and its relevance to the study.

Stress is tension or pressure. Stress is a natural part of living our life.

Any change, good or bad, big or small, can cause stress. Big changes or events in our life--like getting married, a serious illness, changing jobs--can cause stress. Small events- like losing your keys, having a birthday, having a flat tire, or needing to get your errands done before picking up your children--can also cause stress.

What kinds of things make you feel stressed?

Why are we talking about stress in the Lifestyle Balance program? Because **many people react to stress by changing their eating and activity habits**. Some people eat and drink too much as a way to deal with stress. Others may stop eating. Some people become very inactive and withdrawn.

What is it like for you when you get stressed?

If the participant does not provide examples, mention one or two situations that are typically stressful (such as being under a deadline at work, illness, being faced with unexpected responsibilities such as a sick child or car repair). Ask how the participant feels or reacts. Based on the response, point out any physical and emotional symptoms (headache or muscle tension) and behavioral changes that might affect eating and activity.

- Do you get any physical symptoms like a headache or stomach ache or muscle tension?
- Do you change your behaviors when you feel stressed?
- Do you eat more when you are stressed?
- Do you change the kinds of food you eat?
- Do you change how active you are or the kind of physical activities you do?

Discuss ways to prevent stress.

An ounce of prevention is worth a pound of cure, and this is certainly true when it comes to stress. The best approach is to **prevent stress whenever you can**. Here are some ideas:

1. Practice saying, “No.”

Practice saying “No” when someone else asks you to do something you don’t want to do. Say “Yes” only when it is important to **you**.

Saying “No” can be hard. It causes some tension or stress. But that stress is usually short-lived. If you say “Yes,” you may have hours, weeks, or months of stress as you do whatever you agreed to do.

2. Share some of your work with others, both at home and at work.

Delegate what you can to someone else. For example, your spouse and children might be able to help clean the house, cut the lawn, shop for food, prepare meals, and do laundry. A co-worker might be able to help you with an overwhelming project at work.

Sharing work doesn’t mean you’re being irresponsible. Giving responsibility to others, even if they aren’t as experienced as you, gives them a chance to learn, participate, and gain experience. One warning: Don’t expect them to be perfect. Criticizing the efforts of others who are trying to help can

be another source of stress. Instead, support them for their efforts and be patient as they gain skills.

3. **Set goals you can reach.**

Sometimes we create our own stress by trying to be perfect. If you set reasonable goals, you are more likely to succeed. When you succeed, you are less likely to feel stressed. Remember, we talked about this when we discussed negative thoughts—if you try to be perfect, you probably won't succeed!

Periodically, take a good look at the demands you are placing on yourself. Ask yourself, "Am I expecting myself to do more than anyone could possibly do?"

4. **Take charge of your time.**

Make schedules with the real world in mind. Don't try to accomplish in 30 minutes what realistically will take an hour. Take a good look at your to-do list, eliminate what isn't essential, and give yourself a realistic amount of time to accomplish the rest.

Get organized. Chaos is very stressful. It's also inefficient. Devote some time every day to getting organized, and you will save time and stress in the long run.

5. **Use the steps for solving problems.**

If changing your eating and activity habits is causing stress, take action. Use the steps to solving a problem that we discussed in an earlier session:

- Describe the problem in detail. Discuss it with your family or friends if they are involved.
- Brainstorm your options.
- Pick one option that is very likely to work and that you can do.
- Make an action plan.
- Then try it and see how it works.

Continue the process until you find a solution. Sitting on problems can cause even more stress. Solve them instead and move on.

6. **Plan ahead.**

Think about what kind of situations are stressful for you. These are times when you are at high risk, so plan ahead for how to handle them or work around them. For example, are holidays especially stressful for you? If so, plan some ways to make your life easier during the holidays. Examples: Buy frozen meals to have on hand for busy days. Decide what parts of decorating the house are not essential to you and spend that time relaxing instead.

7. **Keep things in perspective. Remember your purpose.**

Maintain a positive attitude. Think of all the good things in your life. And remember why you joined the study.

8. **Reach out to people.**

Think about who you can turn to for support. **Ask supportive people to help** when you are overwhelmed or need someone to encourage you. We talked about this last week.

9. **Be physically active.**

Many people find that being active helps them cope with stress and feel more relaxed and able to manage stressful situations more smoothly.

Discuss ways to cope with unavoidable stress.

What about the times when you can't avoid stress?

- **First, catch yourself feeling stressed as early as you can.**

We talked before about action or behavior chains and that it's important to try to break them as early as possible. The same is true of stress. If you learn to recognize the signs of stress and catch yourself early in the process, you may have a chance to avoid some of the harmful consequences such as overeating or being inactive.

Do you have any signs when you are getting stressed?

- **Take a 10-minute "time out."**

Develop a new habit of responding to stress with a "time out"--stop what you are doing and take a few minutes for **yourself**. Do whatever you find helpful that doesn't involve food. Examples:

- a. **Move those muscles.** Research has shown that being active relieves tension, reduces anxiety, and counters depression. So when you notice yourself feeling stressed, make yourself go out for 10 or 15-minute of exercise. The distraction and breathing can do a lot to make you feel better.
- b. **Pamper yourself.** Take a bath. Manicure your nails. Massage your feet. Read a magazine. Read the funnies. **Just take out 10 minutes for YOURSELF.**
- c. **Breathe.** Most of us tend to hold our breath when we are under stress, which creates more tension in the body and mind. So when you catch yourself feeling stressed, try this: Take a full, deep breath. Count to five. Then let go of your breath slowly. Let the muscles in your face, arms, legs, and body go completely loose.

Discuss how study may be a source of stress and ways to manage that stress.

We understand that **the study itself and the lifestyle changes we recommend may cause stress**. Changing your behaviors and helping your family to make related changes can create pressure and tension.

Here are some possible ways that the study may cause stress and some examples of how to manage that stress.

Review the work sheet with the participant. Note that some of the possible sources of stress may not apply to the participant--for example, the participant's family may enjoy low-fat foods. Be careful that the review of the work sheet does not create a negative perspective, and help the participant feel able to cope should such stresses arise.

Assign home activity.

How does the study cause you stress? *[Record on work sheet.]* What are some other major sources of stress in your life? *[Record on work sheet.]* Pick one of the examples you've given, and let's make an action plan for either preventing that stress or coping with it.*[Complete the work sheet.]*

For next week:

- Keep track of your weight, eating and activity.
- Follow your action plan.

Then answer the questions on the work sheet (Did it work? If not, what went wrong?) before we meet next time.

Session 16: Ways to Stay Motivated

Objectives:

In this session, the participant will:

- Receive a certificate of participation.
- Review the participant's progress since Session 1, and if not at goal, develop a plan to improve progress.
- Discuss the importance of motivation and ways to stay motivated.

To Do Before the Session:

Review the participant's progress notes since Session 1. Note any plans that were made to improve weight loss and activity level, which strategies were used, and which were successful or not successful. If the participant is not currently at goal for weight loss and/or activity, refer to the Tool Box for ideas of additional strategies required or optional for particular problems.

If you have copies of some of the participant's past Keeping Track records, review them as well. Note some of the positive changes the participant has made.

Make sure the participant's How Am I Doing? graphs for weight and activity are up to date.

Get materials ready:

- Keeping Track book(s).
- Optional forms for self-monitoring during maintenance, such as the Lifestyle Balance Calendar, if applicable.
- Pages for participant's notebook.
- Lifestyle Balance certificate of participation. There are several versions; choose the version that is appropriate for the participant's level of progress. You may want to print the certificate on special paper and add the participant's name in calligraphy if possible (by computer or by hand). Have the principal investigator at your center sign the certificate before the session.
- Meal plans appropriate for the participant's calorie goal, if applicable.

Weigh the participant. Graph.

Receive and review Keeping Track records. Discuss successes and difficulties in meeting the study goals. Review the last session, including home activities. Graph activity.

Did you have any trouble Keeping Track last week? Were you able to stay under your fat gram budget? Reach your goal for physical activity? Were you able to follow your action plan (to prevent or cope with one source of stress)?

Praise all progress, no matter how small. Discuss barriers and problem solve with the participant. Graph physical activity.

Give the participant a certificate of participation and introduce the upcoming calendar of sessions.

This is the last of the 16 core sessions of the Lifestyle Balance program.

Congratulations! This certificate is to let you know how very important your participation in the study has been during this time.

Sign the Lifestyle Balance certificate of participation and give it to the participant. Personalize it by mentioning briefly some of the particular contributions and efforts that the participant has made.

It's very important to keep in mind that, even though you have finished the first 16 sessions, the **weight loss and physical activity goals remain in place for the rest of the study**. So at our next visit, we'll talk about how we'll work together in the future to help you...

If the participant hasn't reached the goals, emphasize reaching them and then maintaining them for the rest of the study. If the participant *has* reached both goals, emphasize maintaining them and surpassing them if possible because they are *minimum* goals.

Let's set up an appointment for the next visit

If at all possible, make the appointment for one or two weeks from now. Do **not** go to monthly or bimonthly visits at this point (for a detailed discussion of this issue, see the Manual for Contacts After Core, Session 1). Also, do **not** design a general schedule for the after-core period at this point; wait until the first after-core session when you will discuss the frequency of contact in the context of the goals for the after-core.

Review the participant's progress since Session 1, and if not at goal, develop a plan to improve progress.

Today we're going to talk about ways to stay motivated for the long term, to make healthy eating and being active last for a lifetime. But first, let's review your progress since the beginning of the program.

- **What are some of the major changes you've made to be more active?** Include both what you do to reach your goal (that is, those activities you record) and what you do to be more active in general (the lifestyle activity that you don't record, like taking the stairs instead of an elevator).
- **What changes have you made to eat fewer calories and less fat?**

Briefly record on the work sheet some of the changes made by the participant. Be as specific as possible. Praise and encourage the maintenance of these changes.

Have you reached your weight goal? Your activity goal?

Refer to the How Am I Doing? graphs for weight and activity, and check yes or no on the worksheet.

If the participant is **at goal** for weight loss and activity, praise the progress made.

If the participant is **not at goal** for weight loss or activity, praise whatever progress has been made. Encourage the participant to improve, and develop a plan using the work sheet. **Follow the guidelines in the Tool Box as to which strategies are required to address particular problems identified.** For example, some participants may need to be given meal plans at a lower calorie level.

Discuss the importance of motivation.

In programs like Lifestyle Balance, **motivation is crucial to maintaining healthy eating and physical activity for the long term.** But how to stay motivated is **one of the biggest problems people face.**

One reason it's difficult to stay motivated is the fact that many people do well. This sounds ironic--your progress itself makes it hard to *maintain* that progress. But think back to when you first joined the study. *[Tailor the following examples to the individual participant's experience thus far in the program.]* You may have felt tired when you went up stairs and that motivated you to become more active. Now that you're more active, you can climb stairs without difficulty. So that source of motivation (feeling tired when you climbed stairs) is gone.

It's the same for weight. When you first came into the study, your clothes may have been tight and that motivated you to lose weight. If your clothes are looser on you now, you no longer have tight-fitting clothes as a source of motivation.

Discuss ways to stay motivated.

However, it *is* possible to stay motivated for the long term and, as I said, it is very important to maintaining healthy eating and staying active. Here are some things that other people have found helpful.

1. Stay aware of the benefits you've achieved and hope to achieve.

Again, think back to when you first joined the study. What did you hope to achieve?

Record on the work sheet. Refer the participant back to the work sheet from Session 1A,

Remember Your Purpose, and review. Also **acknowledge any costs** that the participant articulates at this point (or that the participant has discussed with you before). Be aware that, throughout the study, participants will continue to weigh the costs versus the benefits of the program as they perceive them.

Have you reached these goals?

Have you received any benefits that you didn't expect?

What would you like to achieve during the next six months of the study? Let's make a list and then you can review these when you need motivation. *[Record.]*

2. **Recognize your successes.**

What changes in your eating and activity habits do you feel proudest of? What has been easier than you thought it would be? What has been harder than you thought it would be?

When you are feeling low on motivation, think about all of these positive changes and give yourself credit for them. Try not to lose the momentum you have reached so far.

3. **Keep visible signs of your progress so you can see how far you've come.**

- **Post a graph of your weight loss and activity on your refrigerator door.** Not only will it keep you aware of your progress, but loved ones will take note and congratulate you for your movement in the right direction.
- **Mark your activity milestones on a map toward a particular goal.** For example, create a simple map of the number of miles it would take to wheel to a favorite vacation spot or tour a favorite city. Mark milestones along the way (the halfway point, a fun museum to stop at along the way, and so on). You might even want to go on an actual vacation at that place when you reach your goal.
- **Measure yourself at monthly intervals.** Keep track of your progress in terms of specific measurements (for example, waist circumference or the number of belt loops).

4. **Keep track of your weight, eating and activity.**

It's common to "drift" away from new habits. You may gradually make small changes in your eating and activity over a long period of time, and not even be aware that you are slowly going back to your old habits. The best way to prevent this and stay in control is to continue to keep track. Keeping track will help you catch changes before they sneak up on you.

Give the participant optional forms for self-monitoring during maintenance, such as the Lifestyle

Balance Calendar, if applicable.

- **Record your activity daily.**
- **Record what you eat this often:** . *[Fill in the blank. The minimum should be one week per month, but some participants may want to or be willing to continue daily self-monitoring.]*
- **Record your weight on.** *[Fill in the blank, for example, "on Monday mornings."]*

If you gain weight, you will need to keep track more often.

5. **Add variety to your routine.**

We've talked before about how to "jump start" your activity plan. Have you added some variety to keep yourself from being bored with staying active? Have you noticed any difference in how you feel about being active?

The same thing is true with eating. You don't need to use the same low fat salad dressing every night. Experiment with new low fat products. Try new recipes and restaurants. Don't approach healthy eating as a chore. It is an art.

What meals, snacks, or particular foods are you most bored with? Can you think of some ways to vary this part of your eating?

Record the participant's ideas on the work sheet. Examples:

- Use seasonings and flavorings to add flavor to lower-fat dishes. (Review the handout on adding flavor without fat.)
- Try a wide range of fruits, vegetables, and grains.
- Include a variety of colors, textures, and tastes on your plate.
- Make one night a week an "ethnic night," "soup night," or "vegetarian night." Experiment with preparing various recipes for these foods.
- If you eat out often, plan more meals at home.
- If you eat at home often, plan more meals out. (Have you stopped eating out because you're trying to lose weight? Has this left you feeling restricted and deprived? Have you stopped inviting friends over to eat or accepting invitations to eat at their homes? Don't deny yourself the pleasure of social eating. Instead, make a plan for how to handle these times, then try your plan, and see how it works. You may make a few mistakes at first, but it's important to know that you **can** eat out and still eat healthy.)
- Share food preparation and dining with others as a way to relax. Invite people over to prepare dinner together. Cook with your children and spouse.
- Plan potluck dinners around a certain theme and share the best recipes you discover as a group.
- You may want to subscribe to a magazine that includes healthy recipes and food ideas, such as Weight Watchers, Eating Well, or Cooking Light.
- Or take a class to learn how to cook, at least the basics.

If the participant expresses interest in learning more about a specific topic such as ethnic cooking or vegetarian eating, address it briefly here and plan to provide more detail at a future meeting or group session.

6. **Set new goals for yourself, and develop ways to reward yourself when you meet each goal.**

The **goal** should be **specific and short-term** (“I will not use butter or margarine on my vegetables this week”). It should also be something that’s not too easy or too hard(something that will present “**just enough**” of a **challenge** for you that you will be able to do it and will also feel that you’ve accomplished something).

The **reward** should be **something that you will do or buy if and only if you reach your goal**. The reward doesn’t need to be fancy or cost a lot of money. It can be something that you normally enjoy doing (like reading the paper or taking a hot bath) with the difference being that you will do it *only if* you reach your goal. For example, “ After I finish exercising, I’ll call my friend and chat.” Then, if you need a boost to keep you going during your exercise, you can think about what you’ll talk about on the phone with your friend.

What are some non-food ways you can reward yourself for reaching a goal?

Record ideas on the worksheet, such as:

- Buy myself fresh flowers,
- Treat myself to a manicure,
- Go to a movie,
- Set some money aside for something you want to buy or do,
- Take a bubble bath,
- Buy a favorite magazine, or
- Take some time for myself. (Specify.)

7. **Create some friendly competition.**

Get a friend or relative to enter into a friendly competition with you. This should be the **kind of competition in which you both win**. For example:

- If you and your friend are both active every day for a month, at the end of the month what will you do?
- If you are active every day for a month and your daughter does her homework every day, at the end of the month what will you treat yourselves to?
- See how many days in a row you can be active for at least 30 minutes. Try to beat yourself. For example, if last month you were active for seven days in a row, see if you can do better this month.

8. **Use me and others to help you stay motivated.**

If you notice that your motivation is dropping, call me. Or call someone else on the Lifestyle Balance staff. Or call a friend or another participant. Everyone has trouble staying motivated sometimes, so we all understand. And we can help each other through the tough times.

9. **Introduce Viterion 100 system.**

We will be contacting you going forward on a biweekly basis to monitor your progress. We will ask you a few questions about your level of exercise and your caloric intake. If we find that you are maintaining your goals, then we will not contact you more than the pre-planned amount. If the responses indicate that you are having a “slip,” then the lifestyle coach will give you a call to see what’s going on and try to help you get back on track.

Train the participant in the use of the Viterion machine and see if he has any questions.

Assign home activity.

Pick one way to stay motivated that you think would be most helpful to you right now. Choose something that is very likely to work and that you can do. Be realistic. Be specific. (*Record on work sheet.*)Let’s **make an action plan** related to that. (*Complete the work sheet.*)For next week, keep track of your eating and activity. Follow your action plan. And answer the questions on the work sheet before you come in for your next session.

WEIGHT MIRROR

General Principles:

- As a component of the Behavioral Intervention, the Internet based freeware, Weight Mirror, will be used to create a 'virtual image' of the participant that is 7% lighter than their measured weight at the onset of the study.
- Visualization of weight loss, in this manner, will be used as a motivational tool.
- A photograph of the participant will be taken at the onset of the study, and uploaded to the Weight Mirror program for virtual image creation. The area of interest on the website will include eyes to knees inclusive of right/left body dimension.
- Original photograph will be used as a reference along with the virtual image, and included in the Lifestyle Manual to be given to each participant
- Photographs will be updated at 6, 12, and 18 months
- <http://makeovr.com/weightmirror/>



Figure 4. A woman with paraplegia before (left) and after (right) a 7% 'virtual' weight loss.

EXTENTION PHASE - MONTHLY INTERVENTION.	
Topic	
Data Collection	<input type="checkbox"/>
Review of self-monitoring records	<input type="checkbox"/>
Review of homework	<input type="checkbox"/>
Introduction of new topics*	<input type="checkbox"/>
Completion of action plan	<input type="checkbox"/>
Scheduling of next meeting	<input type="checkbox"/>

*only on bi-monthly *face-to-face* meeting with life-style coach.

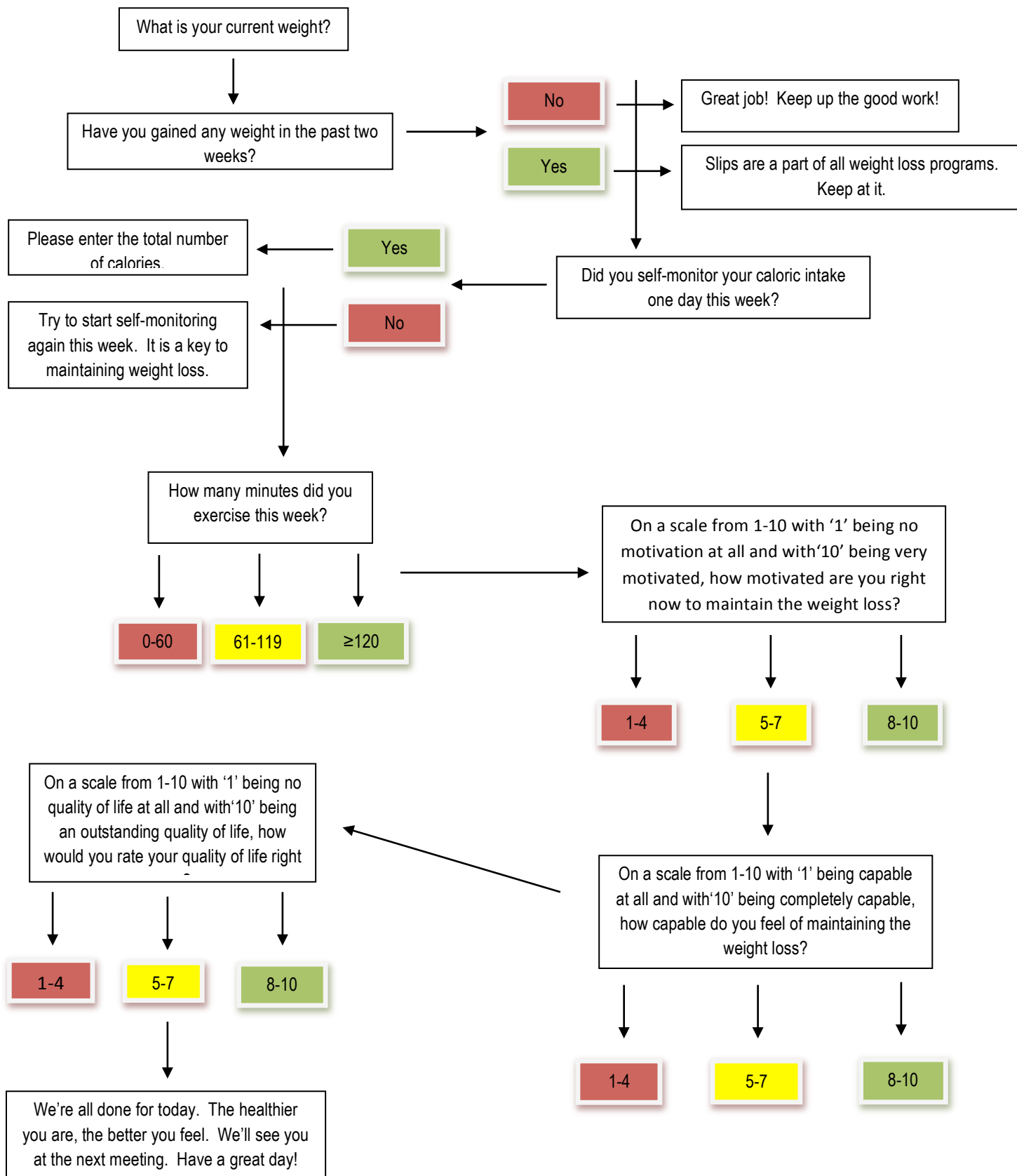
TeleHealth Network:

- Participants will be provided with a **Viterion 100 TeleHealth device** that connects directly to the home phone line.
- **NO** computer, wireless network, modem, or Ethernet link is required.
- Lifestyle coaches can automatically be connected with participants through the TeleHealth system.
- TeleHealth allows patients to receive education and self-management tips **DAILY**.
- Information received by the home TeleHealth device is viewed daily via a secure internet site by an RN/ARNNP-assigned care coordinator.

“Toolbox” Options:

- As employed by the DPP, toolbox options will be utilized by life-style coach’s motivation and adherence to the core and extension lifestyle intervention.
- These options will include awards for compliance, effort, and success.
- Problem solving strategies will be included to mitigate problem behaviors such as poor attendance, insufficient self-monitoring, unmet weight loss goals/maintenance, and unmet physical activity goals.

PROTOCOL FOR PARTICIPANTS USING THE VITERION 100 TELEHEALTH DEVICE



DIETARY DETAILS ARE AS FOLLOWS:

Specific Topics for Dietary Training Curriculum

<p>Session 3</p> <p>Healthy Eating</p>	<ol style="list-style-type: none">1. Learn about healthy eating by discussing the importance of using regular meal patterns and eating slowly.2. Introduce the My Plate from MyPlate.gov. Give tips on specific foods, healthy alternatives, and portions.3. Introduce all 5 food groups and show examples of foods within each group. <p>Activity- Rate Your Plate:</p> <ul style="list-style-type: none">• Participant will pick 4 meals from the previous week. They will fill in the plate per meal for each serving of food they had and what food group it came from.• Participant will answer questions on how their plate looked in comparison to My Plate Sample and if there were any healthier options they could've chosen. <ol style="list-style-type: none">4. Learn how to read a basic food label.<ol style="list-style-type: none">a. Go over serving size, servings per container, calories from fat, ingredient list and percent of daily values.b. Discuss limiting fat, cholesterol added sugar and sodium. <p>Activity: Give sample food label and have participants fill in correct answers from the label provided.</p> <ol style="list-style-type: none">5. To do next week they will:<ul style="list-style-type: none">• Keep track of weight• Fill out rate your plate forms everyday• Answer questions before next session.
<p>Session 4</p> <p>Get to know your Fats</p>	<ol style="list-style-type: none">1. Learn about Unsaturated Fat= <i>"The good guys"</i><ol style="list-style-type: none">a. Monounsaturated fatb. Polyunsaturated fat<p>Activity: Have participants write down 3 healthful fats they eat daily.</p>2. Learn about Saturated Fat= <i>"The bad guys"</i><ol style="list-style-type: none">a. Saturated fatb. Trans fat

	<p>Activity: Have participants write down 3 harmful fats they eat daily then circle one to try to change for the following week.</p> <p>3. Learn how to read Fat on a food label</p> <ul style="list-style-type: none"> Teach what manufactures are required to list on the food label as to what manufactures are voluntarily allowed to list on food labels. <p>Activity: Give 2 sample food labels. Have participants fill in correct answers about fat from the label provided.</p> <p>4. To do next week</p> <ul style="list-style-type: none"> Keep track of the kinds of fat they eat everyday Write down everything they eat, drink and all daily activity Make a plan to change a habit and reach a goal Answer questions before next session.
<p>Session 7</p> <p>Tip the Calorie Balance</p>	<p>1. Learn about the two components of the calorie balance:</p> <ol style="list-style-type: none"> Calories consumed (food, beverages consumed) Calories expended (metabolic process and physical activity) <p>2. To reinforce the importance of maintaining a calorie balance in the weight loss process</p> <ol style="list-style-type: none"> Balancing food calories with activity calories <p>3. Learn how many calories it takes to lose/gain a pound</p> <p>4. Reinforce positive changes made so far</p> <ol style="list-style-type: none"> Changes to be more active Changes to eat fewer calories <p>5. Activity for next week:</p> <ol style="list-style-type: none"> Plan physical activities for the upcoming week Monitor calories consumed Reinforce portion control using portion size guide
<p>Session 10</p> <p>Four Keys to Eating Out</p>	<p>Learn strategies for a successful dining experience outside the home</p> <ol style="list-style-type: none"> Plan Ahead <ol style="list-style-type: none"> Steps to take charge of your eating out experience Ask for what you want <ol style="list-style-type: none"> Strategies to be firm and assertive
	<p>3. Take charge of what's around you</p> <p>4. Choose foods carefully</p> <ol style="list-style-type: none"> Healthy eating pitfall and success clue words <p>5. What's on the menu</p> <ol style="list-style-type: none"> Healthy restaurant menu options Fast food options <p>Activity – Describe a problem when you eat out:</p> <ul style="list-style-type: none"> Identify triggers and proactive solutions <p>6. To do next week</p> <ul style="list-style-type: none"> Continue to self-monitor weight, physical activity Critique action plan

Session 3: **Healthy Eating**

We'll begin today to keep track of your weight:

At every session, mark it on the How Am I Doing.

Your starting weight was _____ pounds.

Your weight today is _____ pounds.

Your goal weight is _____ pounds.

Write your weight down in one place. Keep a track book or your Journal.

Some parts of healthy eating include:

... the way you eat.

A regular pattern of meals is important.

A regular pattern will keep you from getting too hungry and losing control.

Eat slowly. If you eat slowly, you will:

- a) Digest your food better.
- b) Be more aware of what you're eating.
- c) Be more aware of when you're full.

Try pausing between bites. Put down your utensils. Enjoy the taste of your food!

Don't worry about cleaning your plate.

Serve yourself smaller portions to begin with.

... what you eat overall.

Let's start with the Food groups from My Plate.



Balancing Calories

- Enjoy your food, but eat less.
- Avoid oversized portions.

Foods to Increase

- Make half your plate fruits and vegetables.
- Make at least half your grains whole grains.
- Switch to fat-free or low-fat (1%) milk.
- Drink water instead of sugary drinks.

Tips for Foods:

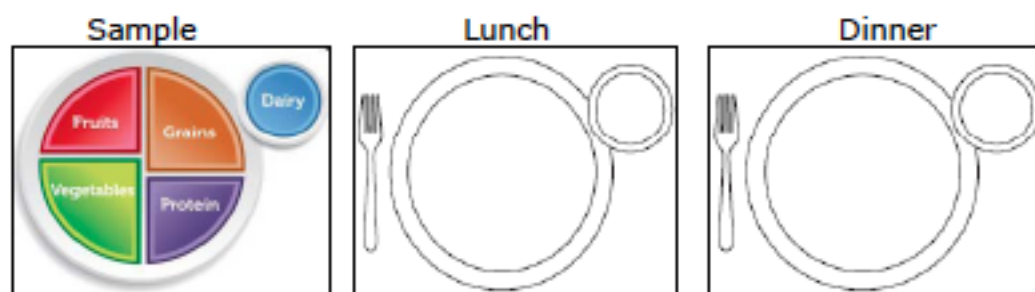
- Buy fresh fruits and vegetables in season. They cost less and are likely to be at their peak flavor.
- Buy packages of fruits or veggies for quick snacks.
- Include a green salad with your lunch and/or dinner every day.
- Try brown rice or whole-wheat pasta instead of white rice or pasta.
 - Check the ingredient list for the words "whole grain" or "whole wheat" to decide if they are made from a whole grain. (Some foods are made from a mixture of whole and refined grains).
- Buy the leanest meat cuts and lean ground meats such as boneless skinless chicken breasts and turkey cutlets.
 - Choose lean or low-fat luncheon meats for sandwiches instead of luncheon/deli meats with more fat, such as regular bologna or salami.
 - Trim away all of the visible fat from meats and poultry before cooking.
 - Drain off any fat that appears during cooking.

<p style="text-align: center;">Vegetable Group</p> <p>Vegetables may be raw or cooked; fresh, frozen, canned. Any vegetable or 100% vegetable juice counts as a member of the Vegetable Group.</p>	<p>Lettuce, spinach, broccoli, carrots, peppers, green beans, cauliflower, celery, cucumbers, Plantains, mushrooms, zucchini, onions, potatoes, and corn. Some Juices like tomato juice or V-8.</p>
<p style="text-align: center;">Grain Group</p> <p>Any food made from wheat, rice, oats, or other cereal grain is a grain product.</p> <p>Grains are divided into 2 subgroups: Whole grains Refined grains.</p>	<p>Whole grains: brown rice, oatmeal, popcorn, wheat tortillas, wild rice, whole wheat bread and breakfast cereals like whole wheat cereal flakes</p> <p>Refined grains: white bread, corn & flour tortillas, couscous, crackers, grits, white noodles and pastas, pitas, pretzels and Breakfast cereals like corn flakes.</p>
<p style="text-align: center;">Fruit Group</p> <p>Fruits may be fresh, canned, frozen, or dried, and may be whole, cut-up, or pureed.</p> <p>Any fruit or 100% fruit juice counts as part of the Fruit Group.</p>	<p>Apples, apricots, bananas, berries, grapes, kiwi fruit, lemons, limes, mangoes, melons, oranges, peaches, pears, papaya, pineapple plums, prunes, and raisins.</p> <p>100% Fruit juices like orange, apple, grape, and grapefruit.</p>
<p style="text-align: center;">Milk Group</p> <p>All fluid milk products and many foods made from milk are considered part of this food group.</p> <p>Most Dairy Group choices should be fat-free or low-fat. Foods made from milk that retain their calcium content are part of the group.</p>	<p>Milk: fat-free (skim), low fat (1%), reduced fat (2%), whole milk, lactose-reduced or lactose free milks Cheese: cheddar, mozzarella, Swiss, parmesan, ricotta, cottage, American Yogurt: fat-free, low fat, reduced fat, whole milk yogurt Milk-based desserts: puddings, ice milk, frozen yogurt, ice cream</p>
<p style="text-align: center;">Protein Group</p> <p>All foods made from meat, poultry, seafood, beans and peas, eggs, processed soy products, nuts, and seeds are considered part of the Protein Foods Group. Beans and peas are also part of the protein group.</p>	<p>Meats, game meats, lean luncheon or deli meats, organ meats, poultry, and eggs. beans and peas: soy beans, split peas, tofu (bean curd made from soybeans), veggie burgers, texturized vegetable protein (TVP), nuts and seeds, seafood</p>
<p>Remember: The amount of each group you need to eat depends on your age, sex, and how physically active you are!</p>	

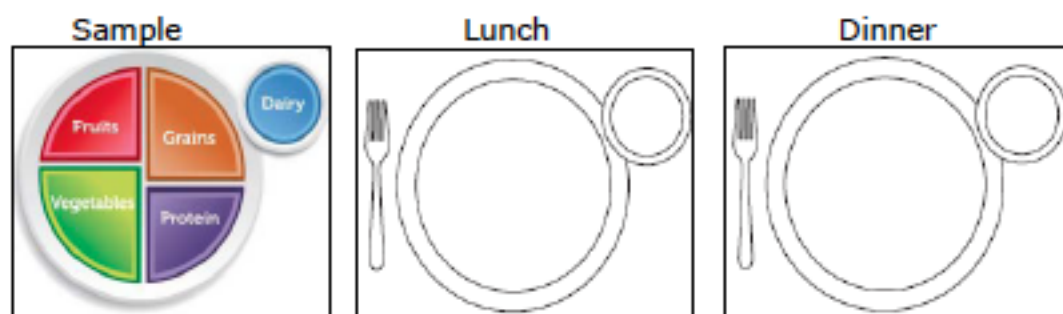
Rate Your Plate (Y)

1. Pick four meals from last week's Keeping Track. Fill in the dates.
2. Fill in each plate for every serving you ate from each food group. The plate beside shows you the minimum number of servings recommended.

Date: ____/____/____



Date: ____/____/____



What could *you* do to better to match My Plate?

Are there healthier options to any foods that you ate? If so, what are they?

Learning how to Read a Food Label

Become a smart shopper by reading food labels to find out more about the foods you eat. The Nutrition Facts panel found on most food labels will help you:

Nutrition Facts		
Serving Size 1 slice (51g) Servings Per Container 6		
Amount Per Serving		
Calories 110	Calories from Fat 90	% Daily Value*
Total Fat 11g		15%
Saturated Fat 2.5g		11%
Trans Fat 2g		
Cholesterol 0mg		0%
Sodium 300mg		12%
Total Carb 15g		5%
Dietary Fiber less than 1g		2%
Sugars 1g		
Protein 3g		
Vitamin A 20%	Vitamin C 4%	
Calcium 45%	Iron 0%	
Thiamin 0%	Riboflavin 0%	
Niacin 0%		

*Percent Daily Values are based on a diet of other people's secrets.

- Find out which foods are good sources of fiber, calcium, iron, and vitamin C

- Compare similar foods to find out which one is lower in fat and calories

- Search for low-sodium and low sugar foods

- Look for foods that are low in saturated fat and trans fats

Serving Size & Servings per Container or Package

- Look here for both the serving size (the amount for one serving), and the number of servings in the package.

- Remember to check your portion size to the serving size listed on the label. If the label serving size is one cup, and you eat two cups, you are getting twice the calories, fat and other nutrients listed on the label.

Calories and Calories from Fat

Find out how many calories are in a single serving and the number of calories from fat. It's smart to cut back on calories and fat if you are watching your weight!

Let the Percent Daily Values Be Your Guide

Daily Values (DV) are average levels of nutrients for a person eating 2,000 calories a day. A food item with a 5% DV means 5% of the amount of fat that a person consuming 2,000 calories a day would eat.

- 5 percent or less is low — try to aim low in total fat, saturated fat, cholesterol, and sodium
- 20 percent or more is high — try to aim high in vitamins, minerals and fiber

Ingredients are listed in order so you get an idea of how much of each ingredient is in the food. When something is listed first, second, or third, you know that this food probably contains a lot of it.

Tips on Food Labels:

Limit Fat, Cholesterol and Sodium:

Eating less of these nutrients may help reduce your risk for heart disease, high blood pressure and cancer:


- Total fat includes saturated, polyunsaturated and monounsaturated fat. Limit to 100% DV or less per day.
- Saturated fat and trans fat are linked to an increased risk of heart disease.
- Sodium — high levels can add up to high blood pressure. Try to stay below 1500 mg per day, and NO higher than 2300 mg per day!

Additional Nutrients

Carbohydrates — there are three types of carbohydrates: sugars, starches and fiber. Select whole-grain breads, cereals, rice and pasta plus fruits and vegetables.

Sugars — simple carbohydrates or sugars occur naturally in foods such as fruit juice (fructose), or come from refined sources such as table sugar (sucrose) or corn syrup.

Now that you know a little more about food labels, you can read up on what you're eating!



Ingredients: Dehydrated Potatoes, Modified Food Starch, Corn Oil, Sugar, Salt, Soy Lecithin, Leavening (Monocalcium Phosphate and Sodium Bicarbonate), and Dextrose.
No Preservatives.

Nutrition Facts	
Serving Size 1 oz. (28g) About 10 chips	
Servings Per Container 10	
Amount Per Serving	
Calories 120	Calories from Fat 30
% Daily Value*	
Total Fat 3g	6%
Saturated Fat 0g	0%
Trans Fat 0g	
Cholesterol 0mg	0%
Sodium 200mg	8%
Total Carbohydrate 21g	7%
Dietary Fiber 3g	6%
Sugars 2g	
Protein 2g	
Vitamin A 0%	Vitamin C 6%
Calcium 4%	Iron 0%
Thiamin 4%	Niacin 6%
Vitamin B6 4%	Phosphorus 6%
Zinc 2%	

*Percent Daily Values are based on a diet of other people's secrets. Your daily values may be higher or lower depending on your calorie needs.

	Calories: 2,000	2,500
Total Fat	Less than 65g	80g
Sat Fat	Less than 25g	35g
Cholesterol	Less than 300mg	300mg
Sodium	Less than 2,400mg	2,400mg
Total Carbohydrate	300g	375g
Dietary Fiber	25g	35g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Let's try this label:

What is a serving of this item? _____

How many servings are there? _____

How many calories are for one serving? _____

How many calories would you eat if you ate 3 servings? _____

Is this a lot for one food item? _____
(Yes! We will explain in a later session)

How much sodium would you get if you ate 3 servings of this item? _____

Is this a lot for one food item? _____

What ingredient does this product have the most of? _____

To do next week:

I will:

- ☐ Keep track of my weight and what I eat.
- ☐ Fill out the Rate Your Plate form every day.
- ☐ Answer these questions before our next session:

Did you make any changes during the week to better match My Plate?

If yes, what were they?

What problems did you have? How did you solve them?

For next week:

Keep track of my food groups by filling in my plate.
Fill in the day of the week. For the meal place B- for breakfast, L- for lunch, or D for Dinner.



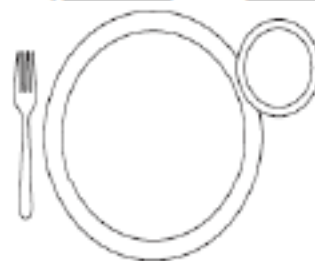
Day _____ Meal _____



Day _____ Meal _____



Day _____ Meal _____



Day _____ Meal _____



Day _____ Meal _____



Day _____ Meal _____



Day _____ Meal _____



Day _____ Meal _____



Day _____ Meal _____



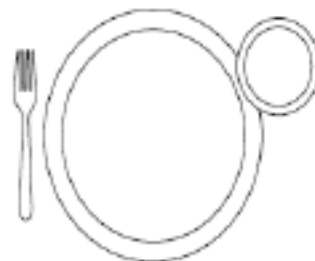
Day _____ Meal _____



Day _____ Meal _____



Day _____ Meal _____



Session 4: Get to know your Fats

Fats, or lipids, are nutrients in food that the body uses to build nerve tissue (like the brain) and hormones. Fats and oils are important parts of a healthy diet, but the type of fat you choose can make a big difference for the health of your heart. By understanding how fats work in the body, knowing the difference between the good guys (unsaturated fat) and the bad guys (saturated fat), you can eliminate excess fat from your diet and eat better for your health.

Two Types of Healthy Fat: “The Good Guys”

- **Monounsaturated fat.** This is a type of fat found in a variety of foods and oils. Studies show that eating foods rich in monounsaturated fats (MUFAs) improves blood cholesterol levels, which can decrease your risk of heart disease. Research also shows that MUFAs may benefit insulin levels and blood sugar control, which can be especially helpful if you have type 2 diabetes.

Foods that are rich in Monounsaturated fat are:

- avocado
- canola oil · olives and olive oil · cashews and cashew butter · sesame seeds
- almonds and almond butter · peanuts, peanut butter and peanut oil



- **Polyunsaturated fat.** This is a type of fat found mostly in plant-based foods and oils. Evidence shows that eating foods rich in polyunsaturated fats (PUFAs) improves blood cholesterol levels, which can decrease your risk of heart disease. PUFAs may also help decrease the risk of type 2 diabetes. One type of polyunsaturated fat, omega-3 fatty acids, may be especially beneficial to your heart. Omega-3s, found in some types of fatty fish, appear to decrease the risk of heart disease. They may also protect against irregular heartbeats and help lower blood pressure levels.

Foods that are rich in Polyunsaturated fat are:

- some salad dressings · walnuts
- corn oil · sunflower oil · some tubs of margarine · pumpkin and sunflower seeds

Name 3 kinds of healthful fats you eat? (Unsaturated)

1. _____
2. _____
3. _____

Two Types of Harmful Fat: "The Bad Guys"

- **Saturated fat.** This is a type of fat that comes mainly from animal sources of food. Saturated fat raises total blood cholesterol levels and low-density lipoprotein (LDL) or "bad" cholesterol levels, which can increase your risk of cardiovascular disease. Saturated fat may also increase your risk of type 2 diabetes.

Foods that are high in saturated fat are:

- skin from chicken and turkey
- lard
- butter
- chocolate
- high fat dairy products such as cream, whole milk, cheese, regular ice cream and sour cream
- high-fat processed meats like ground beef, bologna, hot dogs, sausage, bacon, and spareribs

- **Trans fat.** Most trans fats are made during food processing through heating up of unsaturated fats. Some occur naturally in foods, especially foods from animals. These trans fats are "chemically-altered fats" (companies use them to increase the shelf life of their products).

- Research studies show that trans fat can increase "bad" cholesterol (LDL) and lower the healthy "good" cholesterol (HDL). This can increase your risk of heart disease.

Foods that are high in trans fat are:

- processed foods like crackers, snacks, breads, chips, and baked goods
- candy like caramels and chocolates
- shortening like Crisco
- some fast foods such as French fries and biscuits
- dips



Most of the fat we eat (70% of it) is hidden in foods.

Let's uncover it! Here's a lunch menu:

Fried fish sandwich	5 teaspoons of fat
Large French fries	6 teaspoons of fat
Apple turnover, fried	4 teaspoons of fat
Milkshake, with ice cream	5 teaspoons of fat
Total:	20 teaspoons of fat (That's about 1 entire stick of butter or margarine!)

To help you stay on your weight goal, we'll help you eat healthy.

Make a plan to eat less harmful fat and follow it.

Write down 3 foods you eat that are high in Saturated or Trans fat. Circle one.

1. _____
2. _____
3. _____

Now, what is one way you can cut your saturated fat intake for next week? (There are examples below) Be sure it is something you can do!

1. _____

<i>Instead of...</i>		<i>Replace with...</i>
Bologna, beef or pork, 1 ounce	→ Lower the fat in meats.	Turkey breast, 1 ounce
American cheese, 1 ounce	→ Use low-fat substitutes.	American cheese, low-fat, 1 ounce
Potato chips, 1-ounce bag	→ Eat smaller amounts.	Potato chips, ½ of a 1-ounce bag
Fish, flounder, deep fried, 3 oz	→ Cook in healthy ways.	Fish, flounder, baked, 3 oz.
Mashed potatoes, ½ cup, whole milk and butter	→ Use low-fat flavorings and substitutes.	Mashed potatoes, ½ c, skim milk, and margarine
Green beans, w/bacon, ½ cup	→ Use low-fat flavorings.	Green beans, steamed, ½ cup
Ice cream, premium, ½ cup of ice cream [for a rare treat.]	→ Eat less often.	Frozen yogurt or sherbet ice cream
Regular margarine or butter	→ Eat light option.	Light-spread margarines, or diet margarine
Chicken Nuggets	→ Cook in healthy ways.	Chicken breast, broil, or grill, 3 oz

Now that you know how to read a food label... what does “Total Fat” mean?

Nutrition Facts		
Serving Size	4 cookies (30g)	
Servings Per Container	4	
Amount Per Serving		
Calories 220	Calories from Fat 110	
	% Daily Value ^a	
Total Fat 12g	18%	
Saturated Fat 6g	30%	
Trans Fat 0.5g		
Cholesterol 10mg	2%	
Sodium 70mg	4%	
Total Carbohydrates 25g	8%	
Dietary Fiber 1g	4%	
Sugars 20g		
Protein 3g		
Vitamin A 0%	• Vitamin C 8%	
Calcium 2%	• Iron 4%	
* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.		
	Calories:	2,000 2,500
Total Fat	Less than 65g	80g
Sat Fat	Less than 20g	25g
Cholesterol	Less than 300mg	300mg
Sodium	Less than 2,400mg	2,400mg
Total Carbohydrate	300g	375g
Dietary Fiber	25g	30g
Calories per gram		
Fat 9 • Carbohydrates 4 • Protein 4		

Total Fat on the food label represents the amount of fat in one serving of the product.

Remember Total Fat comes from four sources:

- Monounsaturated Fat > Good Guys
- Polyunsaturated Fat
- Saturated Fat > Bad Guys
- Trans Fat

Note: Manufacturers are *required* to list saturated fat and trans fat as subcategories of total fat and can *voluntarily* list monounsaturated fat and polyunsaturated fat.

There are 12 grams of total fat in one serving of this product

6 grams = saturated fat & 0.5 grams = trans fat.

You can assume the remaining 5.5 grams of fat come from monounsaturated and/or polyunsaturated fat, even though it's not listed on the label.

Question: What if you eat a larger serving than is listed on the label?

Answer: You will be eating more fat (grams) than is listed on the label!!

Read this Food Label:

Nutrition Facts

Serving Size 1 oz. (28g/about 21 pieces)

Servings Per Container 10

Amount Per Serving

Calories 150

Calories from Fat 80

% Daily Value*

Total Fat 9 g	14%
Saturated Fat 2g	10%
Cholesterol 0mg	0%
Sodium 300mg	12%
Total Carbohydrate 16 g	5%
Dietary Fiber less than 1g	1%
Sugars less than 1 g	
Protein 2g	

Vitamin A	0%	Vitamin C	0%
Calcium	0%	Iron	2%

* Percent Daily Values are based on a 2,000 Calorie diet. Your daily values may be higher or lower depending on your calorie needs.

Nutrition Facts

Serving Size 1 cup (228g)

Servings Per Container 2

Amount Per Serving

Calories 280

Calories from Fat 110

% Daily Value*

Total Fat 12g	18%
Saturated Fat 3g	15%
Trans Fat 1.5g	
Cholesterol 30mg	10%
Sodium 470mg	20%
Total Carbohydrate 31g	10%
Dietary Fiber 0g	0%
Sugars 5g	
Protein 5g	

Vitamin A	4%
Vitamin C	2%
Calcium	20%
Iron	4%

*Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

		Calories: 2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	380mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

☐ Look at the Serving size

☐ Look at the Total Fat in grams:

How much is Saturated Fat _____g

How much is Trans Fat _____g

How much Polyunsaturated and Monounsaturated Fat _____g

Let's Try Another Label:

What is the Serving size? _____

What is the Total Fat? _____g

How much Saturated Fat _____g

How much Trans Fat _____g

How much Poly and Monounsaturated Fat _____g

If you had the whole container how much fat is that?

_____ Total fat in 2 servings
 _____ Saturated fat in 2 servings
 _____ Trans Fat in 2 servings

For Next Week:

**Keep track of the fat you eat every day:
“Good Guys vs Bad Guys”**

1. Write down everything you eat and drink.

It's the most important part of changing your behavior.

Spelling is NOT important. What IS important is to:

- Be honest (write down what you really eat).
- Be accurate (measure portions, read labels).
- Be complete (include everything).



Remember: Your lifestyle coach is here to help you!

Next week I will:

Keep track of my weight, what I eat, drink, and my daily activity.

Be active for _____.

Make a plan to change your habit and follow it.

→ Write down in your journal or food diary the foods you circled during today's session.

→ Write down what you will do this week to achieve your goal.
Again, be sure it is something you can do.

What I will need to do to reach this goal:

Problems I might have and what I will do to solve them:

Last week we talked about four types of Fat.

Before the session today, answer these questions:

Did you follow your plan? ___ Yes ___ No ___ Almost

What problems did you have following your plan?

What could you do differently next week?

What I will need to do to reach my goal of eating more healthy fat:

Problems I might have doing this and what I will do to solve them:

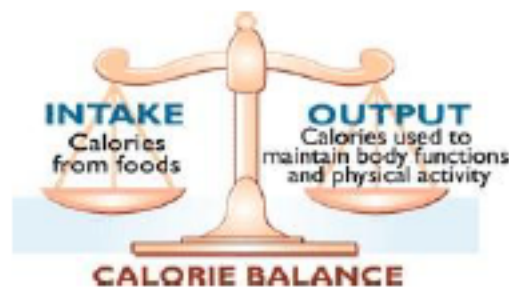
Session 7: Tip the **Calorie Balance**

This session focuses on the TWO main elements in calorie balance:

- calories consumed or eaten
- calories expended

Calorie balance over time is the key to weight management.

Calorie balance refers to the relationship between calories consumed from foods and beverages and calories expended in normal body functions (i.e., metabolic processes) and through **physical activity**. People cannot control the calories expended in metabolic processes, but they *can* control what they eat and **drink**, as well as how many calories they use up during **physical activity**.











<u>Calories in food</u>	
2 Apples	160
Slice of bread w/	160
1 Tbsp peanut butter	

<u>Calories burned during activity</u>	
30-45 minutes of	170*
upper body circuit	
training	

*Patrick L. Jacobs, Edward T. Mahoney, Mark S. Nash, Barth A. Green. Circuit resistance training in persons with complete paraplegia. *J of Rehab Res Dev.* 2002; 39(1): 21-28.

Your weight is a result of the **balance** between
food (calories in) *and* activity (calories out)

	<u>Food Calories</u>	<u>Activity Calories</u>
1. Your weight can stay the same.		
2. You can gain weight.		
3. You can lose weight.		
4. You can reach a new balance at a new weight		



Remember:

- ❖ Foods eaten and being active work together.
- ❖ To lose weight, it's best to eat less **and** be more active.

- ❖ By **TIPPING** the balance you can lose the weight you want!
- ❖ Over time, you can reach a new balance at a new, lower weight.
- ❖ You will keep the weight off by making changes part of your new lifestyle

How much to **tip** the balance?

- ♀ 1 pound of body fat stores equals about 3,500 calories.
- ♀ Slow, steady weight loss (1-2 pounds/week) is the best way to lose body fat.

To lose:	Tip the balance by this number of calories:
1 pound/week	3,500 per week or 500 each day for 7 days
1-1/2 pounds/week	5,250 per week or 750 each day for 7 days
2 pounds/week	7,000 per week or 1,000 each day for 7 days

For permanent weight loss, it's best to eat less **AND** be more active!

Changes you've made so far



To be more active (both to reach your goal and be active in general)

- ☐ _____
- ☐ _____
- ☐ _____



To eat fewer calories

- ☐ _____
- ☐ _____
- ☐ _____

Have these changes *tipped the balance*?

Your weight at the start of Lifestyle Balance:

Weight now:

Expected weight by this time:

You have:

Stayed at the same weight, or gained weight

- ❖ To lose weight, try something else to tip the balance
- ❖ We'll work together to find what works better for you

Lost some weight, but not as much as expected

- ❖ Good. You've made some progress
- ❖ To lose more weight, try something else to tip the balance *farther*.

Lost as much weight as expected (or more)

- ❖ Great! You've tipped the balance
- ❖ Keep tipping the balance, and you'll keep losing weight

To do next week

I will:

1. Keep track of my weight, eating, and activity.
2. Be active for _____.
 - o Try setting aside one block of time OR find 2-3 shorter time periods.
 - o Plan other activities you LIKE to do.

	What I will do	When	Minutes
Mon			
Tues			
Wed			
Thurs			
Fri			
Sat			
Sun			
Total minutes for the week:			

3. Make active lifestyle choices throughout the day
4. To tip the balance further, I will:
 - o Keep track of calories every day
 - o Watch out for foods that are high in empty calories
 - o Be sure to record *everything*
 - o Watch portion sizes

Portion Size Guide



4 dice = 1 oz of cheese



4-oz individual applesauce = $\frac{1}{2}$ cup



1 small potato = 1 computer mouse = or 1 cup vegetables



Small apple = 1 cup of fruit



8 oz yogurt = 1 cup of milk



School milk carton of milk = 1 cup



$\frac{1}{2}$ medium bagel = 1 hockey puck = 1 oz grain



2 Tbsp peanut butter = 1 golf ball



1 cup pasta = 1 baseball



Session 10: Four Keys to Healthy Eating Out

1. Plan Ahead

- Call ahead to ask about low-fat choices
- Pick where you eat out carefully.
- Go somewhere that offers low-fat choices.
- Eat less fat and fewer calories during other meals that day.
- Eat a little something before you go out or drink a large, low-calorie beverage
- Plan what to order without looking at the menu
- Don't drink alcohol before eating
- For parties or dinner parties: Bring something from home to share with others.

2. Ask for what you want. Be friendly and firm

- Ask for the foods you want
 - Ask for lower-fat foods
 - Can foods be cooked in a different way?
- Don't be afraid to ask for foods that aren't on the menu.
- Ask for the amounts you want
 - Ask how much is usually served.
 - Order salad dressing, gravy, sauces, or spreads "on the side."
 - Ask for less cheese or no cheese.
 - Split a main dish or dessert with someone
 - Order a small size (appetizer, senior citizen's, children's)
 - Before the meal, have the server pack $\frac{1}{2}$ of your order to take home.

3. **Take charge of what's around you**

- Ask for one piece of bread per person instead of a bread basket
- Use olive oil instead of butter for your bread

4. **Choose foods carefully**

- Watch out for these high-saturated fat words on



- | | |
|--------------------------------|------------------|
| • Au gratin | • Hollandaise |
| • Breaded | • Parmesan |
| • Buttered or buttery | • Pastry |
| • Cheese sauce | • Rich |
| • Creamed, creamy, cream sauce | • Sautéed |
| • Fried, deep fried, pan fried | • Scalloped |
| • Gravy | • Southern style |

- Look out for these healthier alternatives



- | | |
|-----------|--------------|
| • Baked | • Poached |
| • Broiled | • Roasted |
| • Boiled | • Steamed |
| • Grilled | • Stir-fried |

- Think about what you really *need* to eat
- Trim visible fat off meat
- Take skin off chicken
- Split main dishes with someone to control portion sizes
- Skip the mayonnaise. Use olive oil instead
- In general:
 - Lunch meals should contain no more than 400 calories
 - Dinner meals should contain around 500 calories

What's on the menu?



- You can make healthier choices no matter what kind of restaurant you go to
 - Be sure to ask the waiter how the food is prepared.
 - Note: Most restaurants serve a tossed salad—top with a dash of olive oil and lemon juice or vinegar.



GO! Healthy choices	CAUTION!
Pizza <ul style="list-style-type: none"> • Plain cheese pizza (ask for half the cheese or low-fat cheese). • Onions, green peppers, mushrooms, tomatoes • Grilled chicken 	Pizza <ul style="list-style-type: none"> • Meat toppings (sausage/pepperoni, ground beef) • Extra cheese
Burger Place (fast food) <ul style="list-style-type: none"> • Grilled, broiled, or roasted chicken, without sauce or mayonnaise • Broiled, extra lean burger. 	Burger Place (fast food) <ul style="list-style-type: none"> • Regular hamburger, cheeseburger. • French fries. • Fried fish or chicken. • Mayonnaise-based sauces.
Mexican <ul style="list-style-type: none"> • Heated (not fried) tortillas. • Grilled chicken or beef fajitas • Soft tacos (corn or flour tortillas). • Salsa or Pico de Gallo 	Mexican <ul style="list-style-type: none"> • Enchiladas. • Chili con queso • Fried tortillas, tortilla chips • Sour cream, guacamole • Crispy or crunchy tacos
Chinese and Japanese <ul style="list-style-type: none"> • Stir-fried chicken. • Stir-fried vegetables. • Steamed rice. • Soup. • Teriyaki. 	Chinese and Japanese <ul style="list-style-type: none"> • Egg foo yung. • Fried chicken, beef, or fish. • Fried rice or noodles. • Egg rolls. • Fried won ton. • Tempura.
Italian <ul style="list-style-type: none"> • Spaghetti with meatless tomato sauce • Minestrone soup 	Italian <ul style="list-style-type: none"> • Sausage • Lasagna, manicotti, other pasta dishes with cheese or cream • Fried or breaded dishes (like veal or eggplant parmesan)



GO! Healthy choices	CAUTION!
Seafood <ul style="list-style-type: none"> • Broiled, baked, or boiled seafood with lemon • Plain baked potato 	Seafood <ul style="list-style-type: none"> • Fried fish • Fried vegetables • French fries
Steakhouses <ul style="list-style-type: none"> • Shrimp cocktail • Broiled chicken or fish • Plain baked potato 	Steakhouses <ul style="list-style-type: none"> • Steak (except trimmed lean cuts). • Fried fish or chicken • Onion rings, other fried vegetables • French fries



Fast Food Options

As you embark on your journey towards a healthier lifestyle it is important to be prepared for the occasional obstacle or bump on the road. Although eating fresh, home prepared meals is always best, below are some convenient options that can fit into your healthy plan for those days when you are *on-the-go*.

 Arby's		 Boston Market	
Menu Item	Calories	Menu Item	Calories
Roast Turkey and Swiss Sandwich (1/2)	340	Qtr. White Rotisserie Chicken (1/2 order) with Steamed Veg and New Potatoes	360

 Burger King		 Domino's	
Menu Item	Calories	Menu Item	Calories
BK Veggie Burger (no cheese)	410	Hand tossed Chicken and Veggie (per slice, small)	210
BK Big Fish Sandwich (1/2 order)	320	Hand tossed Pepperoni Pizza (per slice, small)	238
Spicy Chick'n Crisp Sandwich	300		

			
Menu Item	Calories	Menu Item	Calories
KFC Snacker with Crispy Strip	290	Filet O Fish	380
Grilled Chicken Breast (1/2 order) with Green Beans and Mashed Potatoes n' gravy	240	McChicken	360

			
Menu Item	Calories	Menu Item	Calories
Chicken TROPICHOP w/ rice and beans (1/2 order)	265	Fresco Crunch Taco	150
Chicken TROPICHOP w/ rice and vegetables	165	Fresco Soft Taco – Beef	180
Pork TROPICHOP w/ rice and beans (1/2 order)	340	Fresco Bean Burrito	350
Pork TROPICHOP w/ rice and vegetables (1/2 order)	245	Fresco Burrito Suprema – Chicken	350
1/4 Chicken, white meat (no skin), w/ rice and beans (1/2 order)	350	Fresco Burrito Suprema – Steak	340

Describe a problem you have when you eat out

1. Make a positive action plan using one of the 4 keys to eating out

I will: _____

When? _____

I will do this first: _____

2. I will handle roadblocks that may come up by: _____

3. I will do this to make my success more likely: _____

4. How can we help you? _____

To do next week

- 1. Keep track of my**
 - i. Weight
 - ii. Eating
 - iii. Physical activity

- 2. Try my action plan.**
 - i. Did it work?
 - ii. If not, what went wrong? _____



CIRCUIT RESISTANCE TRAINING (CRT).

General principles:

- **CRT** is a mode of training that employs lockstep resistance maneuvers interposed with short periods of un-resisted, high velocity arm work.
- Study participants will undergo **CRT three times per week** on non-consecutive days for **24 weeks**.
- Resistive loads for training during weeks 1 and 2 of each month will be **50%** of the 1-repetition maximal (1RM) values calculated during initial isoinertial strength testing.
- Resistive loads will be increased to 55% and 60% of the 1RM during training weeks three and four for each month, respectively.
- 1RM strength will be assessed as follows:
 - ☐ Subjects will be instructed to perform 8 repetitions of each maneuver with each repetition lasting six seconds (3 seconds concentric, 3 seconds eccentric).
 - ☐ If 8 repetitions are completed in a controlled fashion, weight will be increased and the exercise repeated – incremental increases will be 5 kg (paraplegia) and 2.5 kg (tetraplegia) until 8 repetitions **cannot** be completed.
 - ☐ 1RM will be calculated using the Mayhew regression equation:

$$1RM = Wt / (0.533 + 0.419e^{-0.055 * REPS})$$

where **1RM** is the calculated one repetition maximum strength, **Wt** is the resistance used in the last set where more than three repetitions but less than eight repetitions were completed, and **reps** equals the number of repetitions completed in the last set of testing.

- 1RM will be assessed in the following time schedule:

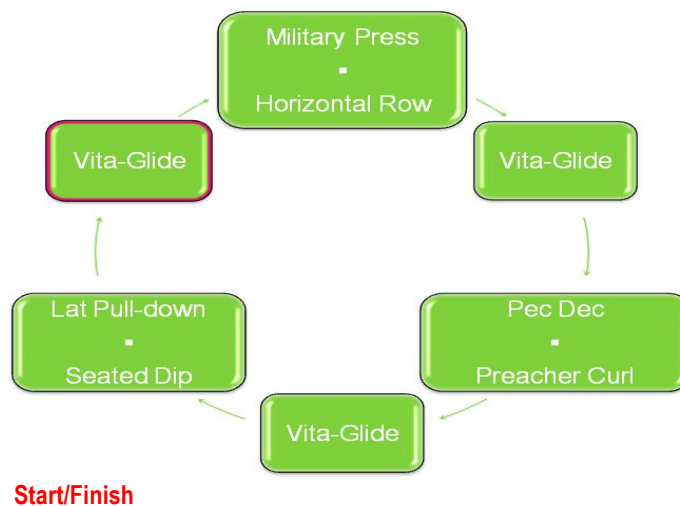
Exercise Maneuver	Upper extremity dynamic strength (1RM)									
	-3	0	1	2	3	4	5	6	12	18
Military press	▪	▪			▪			▪		
Horizontal rows	▪	▪			▪			▪		
Pec dec	▪	▪			▪			▪		
Preacher curls	▪	▪			▪			▪		
Latissimus pull-downs	▪	▪			▪			▪		
Seated dips ("Rickshaw")	▪	▪			▪			▪		

DESCRIPTION OF EXERCISE MANEUVERS UTILIZED IN CRT.

Exercise Maneuver	Description
Military Press	Shoulder abduction with scapular elevation and upward rotation starting from the fully adducted and depressed position.
Horizontal rows	Shoulder horizontal abduction with scapular adduction starting from a position of maximum forward reach.
Pec dec	Should horizontal adduction while in external rotation to the midline, from the maximum tolerated horizontal abduction in external rotation.
Preacher curls	Elbow flexion supported on an inclined pad from the fully extended position.
Latissimus pull-downs	Shoulder adduction with scapular downward rotation and depression starting from the maximal upward reach position.
Seated dips ("Rickshaw")	Shoulder flexion, scapular depression, and elbow extension while maintaining arms as near the body as possible, from the fullest allowed point of shoulder joint extension, scapular elevation, and elbow flexion.

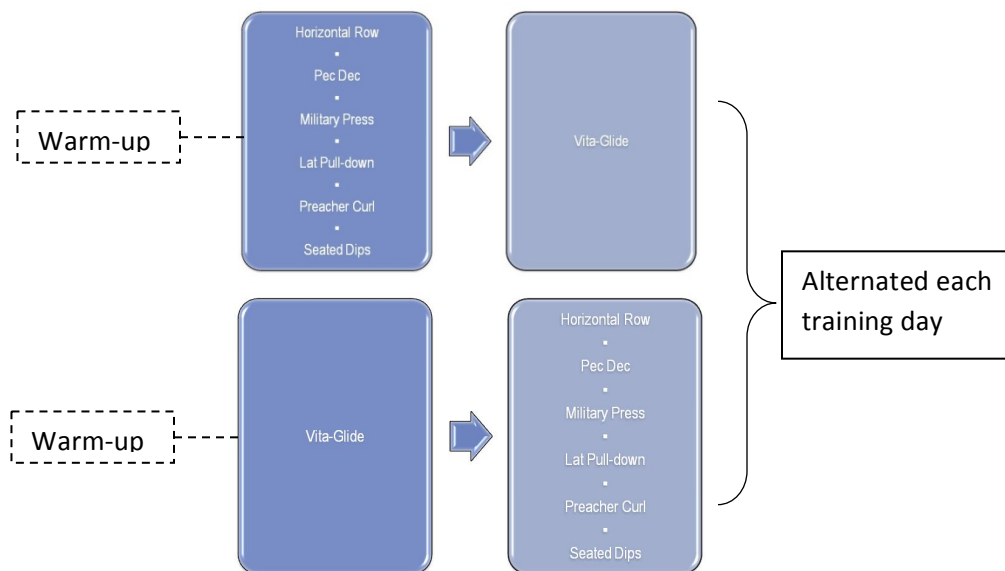
CRT training session design:

- Each training session will be preceded by a 2-minute warm-up on a Vita-glide® arm ergometer.
- Resistance exercises will be performed in pairs (2 maneuvers in succession) each incorporating 10 repetitions of each maneuver lasting six seconds (3 seconds concentric, 3 seconds eccentric).
- Two minutes of endurance exercise is then interposed using a Vita-glide® arm ergometer at a cadence of 50 rpm without applied resistance
- Two more resistance maneuvers are performed.
- These activities are alternated until the participant has rotated through each resistance station **three times**.



Modifications to CRT for participants with tetraplegia:

- Adaptations to work-out for persons with tetraplegia as high as the C5 level.
- Resistance maneuver order is altered to reduce time needed for changing the resistance stations.
- Resistance and endurance exercises are performed in contiguous time blocks – order of exercise (i.e. resistance and endurance) are alternated on each training day.
- Each training session will be preceded by a 10-minute warm-up on a Vita-glide® arm ergometer.
- Each resistance station will be performed **twice only**.



Upon completion of this course the participant will be able to:

1. Identify the key health-based outcome of the landmark multicenter Diabetes Prevention Program.
2. Know three component interventions of an SCI population-relevant version of the DPP.
3. Know the impact of a DPP lifestyle intervention on cardiometabolic disease risks in persons with paraplegia.

Intensive Lifestyle Intervention after Paraplegia Significantly Reduces Cardiometabolic Risks: A Two-Subject Case Report

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Objective: The landmark Diabetes Prevention Program (DPP) reported that body mass (BM) reduction of $\geq 7\%$ through lifestyle intervention (LI) delayed diabetes onset. We've adapted the LI for persons with SCI. This two-subject case examines effects of the clinical testing phase on component risks for cardiometabolic syndrome.

Design: Pre-post intervention.

Participants/methods: **Case 1:** [57 y/o ♂, T5 AIS-A, 29 years, obese/pre-diabetic], and **Case 2:** [43 y/o ♂, T7 AIS-A, 8 years, morbid obesity/insulin resistant] underwent a 6-month LI program incorporating 3x weekly circuit resistance training, Mediterranean-style diet (1200-2000 kcal/day), and 16 structured educational sessions with a lifestyle coach.

Results: **Case 1:** Post-LI cardiopulmonary endurance increased by 10.3%, accompanied by 8.1% lower BM. HbA1c was lowered from 7.2 to 6.4%, with 36.5% reduction in insulin resistance (as HOMA-IR), and 20% reduction of fasting blood glucose. Fasting triglycerides were reduced from 120 to 97 mg/dL, LDL-C lowered by 12.7%, and global CVD risk (as total cholesterol:HDL ratio) was reduced by 13.6%.

Case 2: Post-LI endurance increased by 25.1%, accompanied by 7.3% lower BM. HbA1c was lowered from 6.1 to 5.8%, with 40.9% reduction in HOMA-IR. Fasting triglycerides were reduced by 32.2%, LDL-C lowered by 11.9%, and TC:HDL ratio lowered by 19.8%.

Conclusions: Success was achieved in surpassing the 7% DPP BM criterion for diabetes prevention, accompanied by improved insulin sensitivity and reduced lipid-related risks. Larger sampling and follow-up testing for treatment durability are needed to affirm program success.

Support: Funded by Department of Defense CDMRP #SC090095(W81XWH-10-1-1044).

Upon completion of this course the participant will be able to:

1. Identify the key health-based outcome of the landmark Diabetes Prevention Program.
2. Know two reasons this outcome is relevant to persons with chronic SCI.
3. Know three component interventions of an SCI population-relevant version of the DPP.

A Population-Relevant Lifestyle-Intensive Intervention for Diabetes Prevention after SCI

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Objective: The Diabetes Prevention Program (DPP) was a landmark multicenter trial that reported $\geq 7\%$ reduction of body mass delayed onset of diabetes. As overweight body habitus and diabetes are prevalent after SCI, we are examining effectiveness of DPP foundations in an SCI cohort. The initial trial objective was to repurpose DPP principals for SCI-population relevance and lifestyle-intensive intervention.

Design: Multi-center randomized placebo-controlled trial with multiple time-point assessments.

Participants/Methods: 64 men and women (18-65 years) with SCI (>1 year; AIS A-C; C5-L1) having 2 (or more) component risks for cardiometabolic syndrome.

Results: We have designed an SCI-relevant program incorporating 3x/week supervised circuit exercise for 6 months and a client-directed quasi-supervised extension for another year. Half of participants will also adopt Mediterranean-style diet (1200-2000 kcal/day) and receive: (1) 16 individualized educational sessions (8: diet/exercise goals and self-monitoring; 8: psychological/social challenges to behavioral modifications, cognitive behavioral therapy, and motivational interviewing) with a lifestyle coach (6 months), (2) bi-monthly lifestyle coach interaction and weekly home TeleHealth Network monitoring (Viterion 200, Bayer Healthcare) (both 12-months), and (3) A personal virtual image rendering of 7% body mass reduction as visual motivation. (Weight Mirror[®]) Activities are supported by a toolbox of behavioral motivations and rewards for weight loss, programmatic compliance, and outcome success.

Conclusions: We report success in achieving design objectives with participant satisfaction, which permits us to advance and test intervention success and durability on body mass, fasting and postprandial metabolites (lipids, glucose, insulin), and HRQoL.

Support: Department of Defense #SC090095(W81XWH-10-1-1044).

Evidence-based and heuristic approaches for customization of care in cardiometabolic syndrome after spinal cord injury

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Component and coalesced health risks of the cardiometabolic syndrome (CMS) are commonly reported in persons with spinal cord injuries (SCIs). These CMS hazards are also co-morbid with physical deconditioning and elevated pro-atherogenic inflammatory cytokines, both of which are common after SCI and worsen the prognosis for all-cause cardiovascular disease. This article describes a systematic procedure for individualized CMS risk assessment after SCI, and emphasizes evidence-based and intuition-centered countermeasures to disease. A unified approach will propose therapeutic lifestyle intervention as a routine plan for aggressive primary prevention in this risk-susceptible population. Customization of dietary and exercise plans then follow, identifying shortfalls in diet and activity patterns, and ways in which these healthy lifestyles can be more substantially embraced by both stakeholders with SCI and their health care providers. In cases where lifestyle intervention utilizing diet and exercise is unsuccessful in countering risks, available pharmacotherapies and a preferred therapeutic agent are proposed according to authoritative standards. The over-arching purpose of the monograph is to create an operational framework in which existing evidence-based approaches or heuristic modeling becomes best practice. In this way persons with SCI can lead more active and healthy lives.

Keywords: Drug therapy, Exercise therapy, Metabolic cardiovascular syndrome, Nutrition therapy, Spinal cord injuries, Atherogenesis, Tetraplegia, Paraplegia

Introduction

The health hazards imposed by all-cause cardiovascular disease (CVD) and co-morbid endocrine disorders in persons with spinal cord injuries (SCIs) have been the subject of considerable clinical concern and research attention.^{1–4} Although known by various names, the descriptor “cardiometabolic syndrome” (CMS) has been adopted to represent a complex array of these risks, which by evidence-based diagnosis encompass the five component hazards of central obesity, hypertriglyceridemia, low plasma high-density lipoprotein cholesterol (HDL-C), hypertension, and fasting hyperglycemia (Table 1).^{5,6} Left untreated, these disorders incite atherosclerotic plaque formation and premature CVD, and in the process pose a health threat considered

so menacing that clustering of three or more CMS components confers the same health risk as a clinical finding of extant coronary artery disease.⁷

Convincing evidence now supports the threat to persons with SCI for an accelerated trajectory of CMS.^{4,8,9} Component risks of central obesity,^{10–12} impaired fasting glucose and frank diabetes mellitus,^{13–15} and both fasting dyslipidemia^{1,16,17} and exaggerated postprandial lipemia^{18,19} underpin this threat, and are observed earlier in the lifespan of those with SCI than in the general population. Although the described risk profile might appear disheartening for those sustaining SCI, it thus far fails to include the disease-accelerating risks of sedentary lifestyle and physical deconditioning commonly reported after SCI,^{9,20,21} and neglects to consider emerging reports of exaggerated post-injury inflammatory cytokines now thought to be instigators of pro-atherogenic activity.^{22–24} Although

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Table 1 American Heart Association/NCEP Guideline (Updated) for Diagnosis of Cardiometabolic Syndrome⁷

Risk	Criterion
Waist circumference	Men >40 inches (102 cm) Women >35 inches (88 cm)
Fasting triglycerides	≥ 150 mg/dl (1.7 mmol/l)
HDL-C	Men <40 mg/dl (1.03 mmol/l) Women <50 mg/dl (1.29 mmol/l)
Blood pressure	≥ 130/85 mmHg, or use of medication for hypertension
Fasting glucose	≥ 100 mg/dl (5.6 mmol/l), or use of medication for hyperglycemia

the latter risks are not formally included among evidence-based CMS component hazards, their disease-promoting threats are so extensively characterized and firmly entrenched among key CVD risks that they warrant attention as legitimate therapeutic targets in persons with SCI.

Although findings of component risks and risk clustering after SCI might otherwise paint a bleak long-term health picture, lifestyle modification, and medical management of patients with CMS continue to improve as risk-assessment tools become more precise²⁵ and treatment interventions more effectively targeted.²⁶ These tools and treatments are typically tested for population-specific efficacy, thus satisfying the contemporary focus on evidence-based treatments as trustworthy standards that drive health care assessment, intervention, and services. It is also prudent to rely on general population guidelines and best practical suppositions in cases where population-specific assessment is lacking, especially when lack of aggressive primary prevention can allay profound health risks and functional decline. The latter “heuristic” approaches are based on our intuitive judgments, experience, and general discovery,²⁷ and effectively serve where exhaustive testing of tools and treatments has yet to be undertaken. That expressed, the current monograph will examine both evidence-based and heuristic approaches to customized management of CMS in persons with SCI. When possible the discussion will be grounded in the evidence-based disease guidelines of the American Heart Association/National Cholesterol Education Project Adult Treatment Panel III,²⁸ established disease prevention approaches adopting therapeutic lifestyle interventions (TLIs) of diet and exercise, and a last resort adoption of medication as a disease countermeasure when TLI has failed to achieve health goals. A paradigm for management of CMS risk components occurring after SCI is shown in Fig. 1.

CMS Risk Factor:	Overweight or Obesity	Hyperglycemia	Hypertension	Elevated Triglycerides	Low HDL
Evaluation Schedule:	Annually				
Intervention warranted when:	Body Mass Index ≥ 22 kg/m ²	Fasting Blood Glucose ≥ 110 mg/dl	Resting Blood Pressure ≥ 130/85 mm Hg	Fasting Triglycerides ≥ 200 mg/dl	Fasting HDL ≤ 40mg/dl (m) ≤ 50 mg/dl (w)
Primary Lifestyle Intervention (instituted for minimum of 3 months):	Exercise (Table 2) + Mediterranean/DASH-type Diet with caloric restriction				Exercise (Table 2)
Pharmacotherapeutic Intervention if Primary Lifestyle Intervention fails	None currently judged as appropriate	Metformin as first-line agent; used until target is reached	Implement JNC VII guidelines until target is reached	Omega-3 FA, Extended-Release Niacin, or Fibric Acid Derivative until target is reached	Extended-Release Niacin until target is reached

Figure 1 A paradigm for management of CMS risk components occurring after SCI.

Need for dietary therapy

The CMS in humans is broadly influenced by dietary habits and nutritional status. Both may be significantly altered after SCI due to changes in the metabolic milieu (e.g. loss of metabolically active tissue), physical barriers (e.g. access to food shopping and grocery store shelving), environment (e.g. institutional food), functional challenges (e.g. difficulties encountered in preparing food), and social factors (e.g. food provided as comfort by family/friends).²⁹ As persons with SCI already live in an “obesogenic environment”³⁰ before sustaining injuries, this reality and other factors combine to thereafter make healthy nutrition habits all the more challenging. In order to provide recommendations that address the problematic metabolic milieu and associated diseases, dietary intakes and resulting nutritional status of persons with SCI must be identified. Key nutritional factors affecting the metabolic milieu include overall caloric intake and macronutrient composition, the latter focusing on risks imposed by dietary carbohydrate and fat intake. In addition, cholesterol overconsumption can have a major impact on lipid profiles, and some micronutrients and imprudent alcohol intake may similarly constitute dietary health risks.

Dietary intake

Total caloric intake

Data reported since 2008 indicate that men with SCI consume an average of 500–600 fewer kilocalories than the ~2600 kcal standard for men in the general population,^{31,32} whereas caloric intake for women with SCI is about the same or slightly (~100 kcal) lower than the typical intake of ~1800 kcal.^{31,33–35} Previous studies also report a broader range of caloric restriction for men (~300–900 kcal) for men than women

(~300 kcal).^{36–39} Whether these deficits are sufficient to offset gender-dependent reductions of caloric expenditure is unknown due to a lack of information on total caloric expenditure changes following SCI. Nonetheless, data comparing resting energy expenditure and average daily caloric ingestion indicate a surplus intake of ~300–500 kcal per day.^{34,38,39} Although this excess intake may appear insignificant, even a small yet sustained caloric surplus will eventually lead to weight gain, unfavorable lipid profiles, reduced glycemic control, disease, and increased mortality. No differences in caloric or macronutrient intake have been identified for level or completeness of injury, or acute vs. chronic SCI.^{31,33,34,40} This observation contrasts earlier studies that reported low caloric intakes for persons with tetraplegia, but not paraplegia.^{41,42} More precise data on total caloric expenditure in relation to total energy expenditure are needed to make specific dietary recommendations for persons with SCI, and better matching of caloric intake and expenditure should represent a primary goal of dietary therapy.

Fat and cholesterol intakes

Despite a lower intake of kilocalories, most (not all)⁴³ studies report that persons with SCI consume levels of fat that approach or exceed the recommended level.^{31,32,34–38,40,44} Unlike overall caloric intake, percent macronutrient intake appears similar in men and women.^{31,33,40} Saturated fat intakes are also at the high end of, or beyond the recommended limit (<10% of total calories,^{31,32,36,37,40} although several studies reported a decline with duration of injury.^{44,45} High fat intake is commonly associated with weight gain, and particularly high saturated fat intakes appear to negatively affect metabolic profiles and chronic disease outcomes.^{46,47} There is also evidence for a direct relationship between high fat intake and serum triglycerides (TGs) in persons with SCI.⁴⁴ Unlike total and saturated fat intakes, persons with SCI tend to be below the recommended limit for cholesterol intake (<300 mg).^{32,36,37,40,44}

Carbohydrate intake

Carbohydrate intake after SCI appears to fall within recommended ranges of 45–55% total calories according to recent studies.^{31,33–35,40} However, most persons with SCI are below recommended intakes of fruit and vegetable servings, and have excess intake of simple carbohydrates. Both are robustly associated with unfavorable metabolic profiles.^{36,40,48} Given these data, it is not surprising that fiber intakes are low^{34,36,48} even among women.^{31,33,37,40} This is of particular relevance to

persons with SCI as fiber consumption has been related to levels of the cardioprotective high-density lipoprotein (HDL) cholesterol.^{49–52} However, high-fiber diets (20–30 g/day) may stimulate undesirable changes in bowel function that differ from the non-disabled population, which may render high fiber diets impractical for persons with SCI.^{33,53,54} Future studies will need to determine the best ratio and sources for simple and complex carbohydrates that satisfy specific nutrient needs after SCI.

Micronutrients and alcohol

Despite having intake of multivitamin and mineral supplements that typically rival those of the general population, low intakes of several micronutrients have been reported for a significant proportion (i.e. >10%) of the SCI population. These are summarized in Table 2, and include vitamins A, B₅, C, D, E, and K, biotin, calcium, chloride, chromium, copper, folate, iodine, molybdenum, magnesium, niacin, potassium, riboflavin, thiamin, and zinc.^{31,33,34,36,42,48,57} Occasional differences based on gender, injury level, or injury completeness have been reported, although detailed information on this dietary attribute remains scarce.^{31,33,37} Micronutrient status may also be suboptimal in the acute phase of recovery from injury, but improve over time.⁵⁵ Almost all of the above listed micronutrients have been linked to glycemic and/or lipid profiles,^{58–71} but a detailed exploration of these deficiencies and their association with CMS risks of dysglycemia and dyslipidemia exceeds the scope of this monograph. In addition, only a few of these deficiencies have consistently been reported to be prevalent in persons with SCI over the last 10 years. The strongest evidence for deficiencies in a substantial part of the SCI population is available for vitamin B₅, C, D, E, and biotin.^{31,33,34,36,56}

Another dietary component that may have significant impact on the metabolic milieu is alcohol. Low-to-moderate levels of daily alcohol intake (≤ 0–25 g/day) have been associated with decreased coronary heart disease, largely due to positive effects on cholesterol profiles, particularly elevated HDL.^{72–74} Although higher for men than for women, and for people with paraplegia compared with tetraplegia, overall mean alcohol consumption was reported to be low (<10 mg/day) among persons with SCI.³¹ However, there are several limitations of self-report data (as used in most studies on alcohol intake) such as recall bias and underreporting.^{75,76} Despite the low reported average, intake heavy drinking and alcohol abuse are more prevalent in the SCI than the general population.^{75,76} Although a detailed evaluation of alcohol abuse goes beyond the scope of this

Table 2 List of micronutrients with at least one study reporting deviations from recommended intake

Micronutrient	Study	Sample	Intake status	RDA* (18–50 years)	
				Female	Male
Vitamin A	Peiffer <i>et al.</i> ⁴¹	17 male, 1 female (18–80 years)	Average above recommendation	700 µg	900 µg
	Laven <i>et al.</i> ⁵⁵	46 male, 5 female (18–60 years)	62% deficient		
	Levine <i>et al.</i> ³⁷	24 male, 9 female (10–50+ years)	Male average intake below recommendation		
	Moussavi <i>et al.</i> ⁵⁶	79 male, 31 female (22–82 years)	16% below reference range for serum levels		
	Walters <i>et al.</i> ³³	63 male, 14 female (19–70+ years)	92% of males and 57% of females below recommendation		
	Perret <i>et al.</i> ³⁴	18 male, 6 female (22–48 years)	Average above recommendation		
Vitamin B5 (pantothenic acid)	Groah <i>et al.</i> ^{27,31}	61 male, 12 female (20–73 years)	Average below recommendation	N/A	
	Perret <i>et al.</i> ³⁴	18 male, 6 female (22–48 years)	Average below recommendation		
Vitamin B6	Levine <i>et al.</i> ³⁷	24 male, 9 female (10–50+ years)	Average above recommendation**	1.3 mg	1.3 mg
	Walters <i>et al.</i> ³³	63 male, 14 female (19–70+ years)	24% of males below recommendation		
	Perret <i>et al.</i> ³⁴	18 male, 6 female (22–48 years)	Average above recommendation		
Vitamin C	Peiffer <i>et al.</i> ⁴¹	17 male, 1 female (18–80 years)	Average above recommendation	75 mg	90 mg
	Barboriak ⁴²	37 male (average 33 years)	Average above recommendation		
	Laven <i>et al.</i> ⁵⁵	46 male, 5 female (18–60 years)	25% deficient in plasma values (2–4wk post-injury only)		
	Levine <i>et al.</i> ³⁷	24 male, 9 female (10–50+ years)	Average above recommendation		
	Moussavi <i>et al.</i> ⁵⁶	79 male, 31 female (22–82 years)	37% below reference range for serum levels		
	Tomey <i>et al.</i> ³⁶	95 male (20–59 years)	25% below recommendation		
	Groah <i>et al.</i> ^{27,31}	61 male, 12 female (20–73 years)	Average above recommendation		
	Walters <i>et al.</i> ³³	63 male, 14 female (19–70+ years)	52% of males, 14% of females below recommendation		
	Perret <i>et al.</i> ³⁴	18 male, 6 female (22–48 years)	Average below recommendation for males		
Vitamin D	Groah <i>et al.</i> ^{27,31}	61 male, 12 female (20–73 years)	Average below recommendation	15 µg	15 µg
	Perret <i>et al.</i> ³⁴	18 male, 6 female (22–48 years)	Average below recommendation		
Vitamin E	Levine <i>et al.</i> ³⁷	24 male, 9 female (10–50+ years)	Average below recommendation	15 µg	15 µg
	Moussavi <i>et al.</i> ⁵⁶	79 male, 31 female (22–82 years)	“Significant proportion” below serum reference range (average within range)		
	Groah <i>et al.</i> ^{27,31}	61 male, 12 female (20–73 years)	Average below recommendation		
	Perret <i>et al.</i> ³⁴	18 male, 6 female (22–48 years)	Average below recommendation		
Vitamin K	Groah <i>et al.</i> ^{27,31}	61 male, 12 female (20–73 years)	Average recommended intake	90 µg	120 µg
	Perret <i>et al.</i> ³⁴	18 male, 6 female (22–48 years)	Average above recommendation		
Biotin	Groah <i>et al.</i> ^{27,31}	61 male, 12 female (20–73 years)	Average below recommendation	N/A	
	Perret <i>et al.</i> ³⁴	18 male, 6 female (22–48 years)	Average above recommendation		

Continued

Table 2 Continued

Micronutrient	Study	Sample	Intake status	RDA* (18–50 years)	
				Female	Male
Calcium	Peiffer <i>et al.</i> ⁴¹	17 male, 1 female (18–80 years)	Average at or above recommendation	1000 (mg)	1000 (mg)
	Levine <i>et al.</i> ³⁷	24 male, 9 female (10–50+ years)	Average below recommendation		
	Tomey <i>et al.</i> ³⁶	95 male (20–59 years)	Average below recommendation (43% below “safety level”)		
	Groah <i>et al.</i> ^{27,31}	61 male, 12 female (20–73 years)	Average below recommendation		
	Perret <i>et al.</i> ³⁴	18 male, 6 female (22–48 years)	Average at recommendation		
Chloride	Groah <i>et al.</i> ^{27,31}	61 male, 12 female (20–73 years)	Average below recommendation	N/A	
Chromium	Groah <i>et al.</i> ^{27,31}	61 male, 12 female (20–73 years)	Average below recommendation	N/A	
Copper	Laven <i>et al.</i> ⁵⁵	46 male, 5 female (18–60 years)	11% of plasma levels below recommendation	900 µg	900 µg
	Levine <i>et al.</i> ³⁷	24 male, 9 female (10–50+ years)	Average above recommendation**		
Folate	Laven <i>et al.</i> ⁵⁵	46 male, 5 female (18–60 years)	Average of plasma levels above recommendation	400 µg	400 µg
	Levine <i>et al.</i> ³⁷	24 male, 9 female (10–50+ years)	Average below recommendation		
	Tomey <i>et al.</i> ³⁶	95 male (20–59 years)	33% below recommendation		
	Groah <i>et al.</i> ^{27,31}	61 male, 12 female (20–73 years)	Average below recommendation (males only)		
	Walters <i>et al.</i> ³³	63 male, 14 female (19–70+ years)	75–79% below recommendation		
Iodine	Perret <i>et al.</i> ³⁴	18 male, 6 female (22–48 years)	Average below recommendation		
	Groah <i>et al.</i> ^{27,31}	61 male, 12 female (20–73 years)	Average below recommendation	N/A	
Iron	Peiffer <i>et al.</i> ⁴¹	17 male, 1 female (18–80 years)	Average above recommendation	18 mg	8 mg
	Tomey <i>et al.</i> ³⁶	95 male (20–59 years)	“Nearly everyone” met recommendation		
	Groah <i>et al.</i> ^{27,31}	61 male, 12 female (20–73 years)	Average above recommendation		
	Walters <i>et al.</i> ³³	63 male, 14 female (19–70+ years)	Average above recommendation		
	Perret <i>et al.</i> ³⁴	18 male, 6 female (22–48 years)	Average below recommendation		
Molybdenum	Groah <i>et al.</i> ^{27,31}	61 male, 12 female (20–73 years)	Average below recommendation	N/A	
Magnesium	Levine <i>et al.</i> ³⁷	24 male, 9 female (10–50+ years)	Average below recommendation	310–320 mg	400–420 mg
	Walters <i>et al.</i> ³³	63 male, 14 female (19–70+ years)	89% of males, 71% of females below recommendation		
	Perret <i>et al.</i> ³⁴	18 male, 6 female (22–48 years)	Average below recommendation**		
Potassium	Barboriak ⁴²	37 male (average 33 years)	Average below recommendation	4700 mg	4700 mg
	Levine <i>et al.</i> ³⁷	24 male, 9 female (10–50+ years)	Average below recommendation		
	Groah <i>et al.</i> ^{27,31}	61 male, 12 female (20–73 years)	Average below recommendation		
	Perret <i>et al.</i> ³⁴	18 male, 6 female (22–48 years)	Average below recommendation		
Thiamin	Peiffer <i>et al.</i> ⁴¹	17 male, 1 female (18–80 years)	Average above recommendation	1.1 mg	1.3 mg
	Barboriak ⁴²	37 male (average 33 years)	Average above recommendation		
	Laven <i>et al.</i> ⁵⁵	46 male, 5 female (18–60 years)	24% below average		
	Levine <i>et al.</i> ³⁷	24 male, 9 female (10–50+ years)	Average above recommendation		
	Walters <i>et al.</i> ³³	63 male, 14 female (19–70+ years)	22% of males, 14% of females deficient		

Continued

Table 2 Continued

Micronutrient	Study	Sample	Intake status	RDA* (18–50 years)	
				Female	Male
Zinc	Levine <i>et al.</i> ³⁷	24 male, 9 female (10–50+ years)	Male average below, females** above recommendation	8 mg	11 mg
	Groah <i>et al.</i> ^{27,31}	61 male, 12 female (20–73 years)	Male average below***, females above recommendation		
	Perret <i>et al.</i> ³⁴	18 male, 6 female (22–48 years)	Average below recommendation for males		

*RDA (Recommended Daily Intake) Dietary Guidelines for Americans 2010.

**Original article reports it as below recommendation but recommendation is different from USDA 2010.

***Original article reports it as within recommendation but recommendation is different from USDA 2010.

manuscript, clinicians should be aware of SCI-related risks associated with alcohol abuse such as pain, acceptance of injury, life satisfaction, and depression^{75,76} For individuals who were already at-risk drinkers prior to injury, it has been suggested that the early period after SCI may present a “window of opportunity” for effecting a change in alcohol abuse.⁷⁷

Nutritional recommendations

Dietary patterns resembling those of persons with SCI, i.e. relying on high levels of fat and simple sugars, are often associated with dyslipidemia and poor glycemic control. Dietary recommendations to address these risks are usually in line with those adopted for the general population, and have been reviewed elsewhere.^{29,78} Specific recommendations represented by two contemporary dietary strategies, the Mediterranean-style and dietary approaches to stop hypertension diets, are summarized in Fig. 2. Unfortunately, data examining effects of specific dietary interventions in persons with SCI are very limited. In patients with chronic SCI, dietary counseling that adopted recommendations of the American Heart Association resulted in positive changes in lipid profiles,⁷⁹ although changes were limited in scope and of questionable value in altering disease trends. This intervention employed general nutrition advice such as eating an adequate, varied diet and reducing fat intake (particularly saturated fats and cholesterol). At the 16-month follow-up, reductions in Total Cholesterol (TC), low-density lipoprotein (LDL), and TG were observed, but no change in HDL. By contrast, a weight-management intervention consisting of diet, exercise, and behavior modification classes elicited several favorable changes in 16 overweight or obese persons with SCI.⁸⁰ These include reduced caloric, saturated fat, and cholesterol intake as well as increased fiber intake and weight loss with preservation of lean tissue mass. However, no significant changes in lipid profiles were observed, except a decrease in HDL. The latter finding is unusual as we and others have reported positive changes in lipid

profiles with exercise alone, particularly on HDL levels (see exercise section), although a reduction of HDL is not uncommon under conditions of excessive caloric restriction. Other “holistic” interventions showed also no changes in lipid profiles.^{81,82} Future investigation will need to clarify whether there is a consistently negligible or adverse negative effect on lipid profile with these types of interventions and if and why they seemingly differ from exercise only interventions.

Beyond dietary modification alone recent interest has focused on dietary interventions supplementing with omega-3 fatty acids (FAs).^{29,83,84} Six months of omega-3 FA administration in a cohort of 19 men with SCI resulted in a 10-fold increase in plasma omega-3 FA values, but did not affect lipid profile.⁸⁵ However, the 2.25 g/day of omega-3 FA provided in this study may have been below the effective supplement dose range, which has been suggested to be 3–5 g/day.⁸⁶ Given the wide variety of proposed beneficial effects of omega-3 FA including lowering of TG, hypertension, and atherosclerotic plaque formation,^{29,87,88} future investigations with more applicable dosing appear warranted.

In summary, despite low caloric intake compared with the general population, persons with SCI may still experience a caloric surplus, and select foods containing both high levels of fat and saturated fat. When combined with excessive levels of simple carbohydrate and low fiber intake these dietary choices disfavor a healthy metabolic profile. Randomized controlled trials are needed to determine whether diet interventions can successfully modify the undesirable metabolic milieu reported in persons with SCI, and whether these diets can ameliorate component hazards of the CMS.

Exercise/physical activity to enhance metabolic health

Physical activity levels among persons with SCI

Physical activity, exercise, and/or, sport participation rates are low among persons with SCI. Among 985 wheelchair-dependent persons with SCI in the United Kingdom

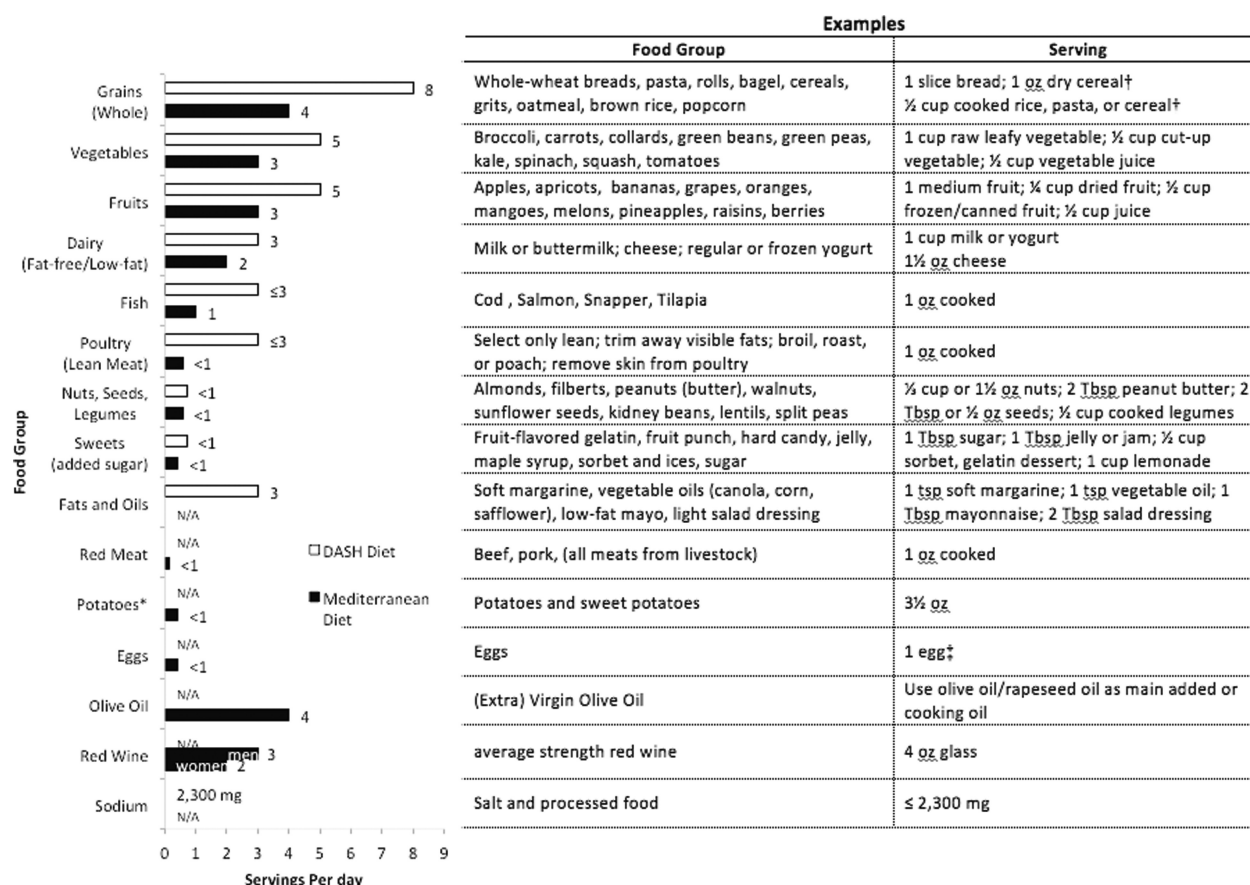


Figure 2 Dietary recommendations based on the Mediterranean and DASH diets. Adapted from <http://www.nhlbi.nih.gov/health/health-topics/topics/dash/followdash.html> and <http://www.patient.co.uk/health/Mediterranean-Diet-Summary-and-Chart.htm>. **Note:** The Mediterranean-style diets are sometimes considered high in fat content and calories for sedentary populations, although the fats are generally monounsaturated and not the more atherogenic saturated fats. The DASH diet is usually prescribed for hypertension management to a greater degree than fat loss, although high intake of fruits and vegetables in the diet may favor the same weight reduction goals. DASH, Dietary Approaches to Stop Hypertension. *Potatoes and eggs are included in the vegetable and lean meat groups, respectively, for the DASH diet. †Serving sizes vary between $\frac{1}{2}$ cup and $1\frac{1}{4}$ cups, depending on cereal type. Check the product's Nutrition Facts label. ‡Eggs are high in cholesterol, therefore limit egg yolk intake to ≤ 4 per week.

injured at least one year, ~63% reported participating in little (~10%) to no (~53%) weekly sports activity.⁸⁹ Ginis *et al.*⁹⁰ corroborated this low rate of physical inactivity. Among 695 non-ambulatory community-dwelling Canadians with SCI, 50% reported no leisure time physical activity (LTPA) in the preceding 3 days.⁹¹ Among the 50% who engaged in LTPA, median activity time was 33 minutes per day. Similar SCI-specific information is not available for the United States. However, 2009–2010 data from a population-based survey of community dwelling persons in the United States (National Health Interview Survey) indicated 50% of persons with a disability report no LTPA in the preceding month.⁹² Collectively, these data confirm the widespread belief that physical inactivity is highly prevalent among persons with SCI.

Physical activity and metabolic health in SCI

Although physical inactivity is rampant among persons with SCI, a growing body of scientific evidence suggests a beneficial impact of physical activity on metabolic health, primarily on fasting lipids. However, little-to-no research has addressed whether exercise/physical activity can reduce fat mass and/or attenuate systemic inflammation among persons with SCI. We have limited our summary of the possible benefits of physical activity to studies examining upper extremity exercise. Although the metabolic benefits of lower extremity functional electrical stimulation and body weight supported treadmill training have been evaluated, these therapies are cost prohibitive, less widely available than voluntary arm exercise, and are not widely available for use by persons with SCI.

Physical activity to improve dyslipidemia and glucose/insulin homeostasis

Two studies have demonstrated that upper extremity based, moderate (or greater) intensity exercise performed for 30–45 minutes three times weekly for 8–12 weeks effectively improves fasting lipids in persons with SCI.^{93,94} An early study by Hooker *et al.*⁹⁵ reported improved fasting lipids after 8 weeks of moderate intensity wheelchair ergometer propulsion performed three times weekly for 20 minutes daily. Activity/rest interval type programs may also be effective in lipid and glyce-mic management, as de Groot *et al.*⁹⁶ demonstrated that 8 weeks of three times weekly moderate intensity “interval” training improved fasting lipids and improved insulin sensitivity. The “intervals” consisted of three minutes of moderate intensity arm exercise followed by 2 minutes of rest, repeated for 1 hour, for 36 accumulated minutes of activity, with the goal of maintaining an intensity at 70–80% of heart rate reserve. An interval-based approach may be an ideal approach to enable use of high-intensity exercise among deconditioned persons with SCI.

Observational studies widely support the findings of intervention-focused investigations. Cross-sectional studies report more favorable lipid profiles (i.e. higher HDL, lower TG, and reduced LDL) among persons with tetraplegia and paraplegia who are habitually highly active or fit relative to their peers.^{23,97,98} Buchholz *et al.*⁹⁹ reported a lower prevalence of insulin resistance among active than inactive persons with SCI. Observational data from the Dutch longitudinal study suggest a favorable relationship between aerobic power, muscle strength, and HDL, TG, LDL/HDL ratio, and TC/HDL ratio across rehabilitation and the first year of discharge from post-injury rehabilitation.¹⁰⁰

SCI/disability-specific physical activity recommendations

Although an existing body of evidence strongly supports health benefits of physical activity for persons with SCI, it remains insufficient to provide a unified recommendation for this specific disability population.¹⁰¹ We thus defer to authoritative recommendations developed for all persons with a disability (Table 3). Perhaps surprising, the weekly aerobic physical activity and resistance training recommendations to improve health are the same for adults with and without disabilities. The U.S. Department of Health and Human services states, “When adults with disabilities are not able to meet the Guidelines, they should engage in regular physical activity according to their abilities and should avoid inactivity. Adults with disabilities should consult their

health-care provider about the amounts and types of physical activity that are appropriate for their abilities.” The World Health Organization states, “These recommendations can be valid for adults with disabilities. However, adjustments for each individual based on their exercise capacity and specific health risks or limitations may be needed.” At this time, the Canadian Society for Exercise Physiology does not provide recommendations for persons with disabilities. However, recommendations to improve fitness in persons with SCI have been developed by SCI Action Canada, a research-medical-community collaborative effort to advance physical activity participation among Canadians living with a SCI. Those who developed these recommendations noted that there was insufficient evidence to unequivocally conclude that the minimum recommendation to improve fitness were also sufficient to reduce CVD risk.¹⁰²

To improve global health, the U.S. Department of Health and Human Services¹⁰³ and the Canadian Society for Exercise Physiology,¹⁰⁴ recommend adults with disabilities in the 18- to 64-year age range accumulate at least 150 weekly minutes of moderate intensity aerobic physical activity, with bouts of activity spaced across the week. Alternatively, adults can accrue 75 weekly minutes of vigorous intensity aerobic physical activity, or an equivalent combination of moderate and vigorous activity. Any “bout” of moderate or vigorous physical activity lasting 10 minutes or more is counted toward this weekly total. Each of these authoritative bodies also recommends resistance training performed at least twice a week, in addition to the aerobic physical activity goals. To achieve important fitness benefits, SCI Action Canada recommends that persons with SCI should engage in at least 20 minutes of twice-weekly moderate-to-vigorous intensity aerobic physical activity, and engage in strength training another two times a week.¹⁰² Importantly, these groups consistently stress that some activity is better than none, even if weekly goals are not met or the person’s abilities are limited; activity beyond the minimum confers additional health benefits; and that the greatest health benefits occur in those who transition from an entirely sedentary lifestyle to performing any physical activity whatsoever.

Historically, exercise and physical activity recommendations to improve health have focused on the moderate-to-vigorous end of the intensity spectrum as an exercise goal. However, recent recommendations encourage “avoiding” inactivity in addition to achieving the target amounts of weekly moderate-to-vigorous

Table 3 U.S. Department of Health and Human Services and the World Health Organization recommended levels of physical activity for adults aged 18–64 years

Aerobic activity		
Total weekly duration	At least 150 minutes (2 hours, 30 minutes)	At least 75 minutes (1 hour, 15 minutes)
Duration per session	Variable, but at least 10 minutes	Variable, but at least 10 minutes
How many days each week?	Most days of the week	Most days of the week
Intensity each session	Moderate	Vigorous
	Activities that feel somewhat hard, but you can keep doing them for a while without getting tired*	Activities that make you feel like you are working really hard, almost at your maximum, and you cannot do these activities for very long without getting tired*
Type of activity	Any activity which achieves the above	Any activity which achieves the above
AND		
Resistance Training Activity		
Number of days per week	At least 2 days a week	
Number of exercises each day	All major muscle groups	
	If upper and lower body, then 8–10 exercises [†]	
	If just upper body, then 4–5 exercises [‡] , with a focus on shoulder depressors and scapular stabilizers [§]	
For each exercise	At least 1 set of 8–10 repetitions, using enough weight so that you can barely, but safely finish the final few repetitions	

*Intensity description from SCIAction physical activity guidelines for adults with spinal cord injury (<http://www.sciactioncanada.ca/guidelines/>).

[†]Total number of upper and lower body exercises from American College of Sports Medicine/American Heart Association physical activity recommendations.⁹⁹

[‡]Total number of upper body exercises represents our suggestion and is not drawn from an authoritative source.

[§]Recommendation to focus on shoulder depressors and scapular stabilizers from the Consortium for Spinal Cord Medicine Clinical Practice Guideline for Preservation of Upper Limb Function Following Spinal Cord Injury.¹⁰⁰

aerobic physical activity. The “avoiding” inactivity recommendation is based on the goal to limit extended periods of stationary, motionless, e.g. “sedentary”, behavior by engaging in very light to light-intensity, non-exercise, physical activity throughout the day. This recommendation confers meaningful health benefits to all persons regardless of current fitness status or total daily moderate or vigorous physical activity. This paradigm shift provides a powerful opportunity to enhance the health of the SCI community. The barriers to limiting stationary, non-movement behavior such as watching television, sitting at a desk, or surfing the internet, and alternatively engaging in very light to light activity including moving around the house or performing basic daily activities, are much lower than the barriers to engaging in moderate-to-vigorous physical activity several times a week. We direct interested readers to the recent perspective of Manns *et al.*¹⁰⁵ for an in-depth discussion of this paradigm shift, and the implications for persons with a disability.

Need for medical clearance and/or supervised physical activity

Health risks associated with physical activity are outweighed by benefits for most persons with SCI.¹⁰⁶ A

recent evidence-based consensus report defined the needs for both medical clearance and supervised exercise in clinical populations, including SCI.¹⁰⁶ For persons with SCI, they recommend that the following groups seek medical clearance before becoming more physically active: (1) persons less than 6 months post-SCI; (2) persons with established autonomic dysreflexia; (3) persons who experience resting or exertional hypotension; and (4) persons with recurrent or recent (within the previous 6 months) musculoskeletal injury that is worsened by physical activity.¹⁰⁶ Once medically cleared, those who are less than 6 months post-SCI should exercise in a supervised environment with trained exercise personnel.¹⁰⁶ In cases where medical clearance has been obtained, the authors provide no additional guideline for need for supervised physical activity in cases of autonomic dysreflexia or symptomatic hypotension. Individuals with recent or recurrent musculoskeletal injuries that may be worsened by physical activity should exercise under supervision of appropriately trained exercise professionals once medical clearance is obtained. Finally, persons who are unaccustomed to vigorous exercise should be supervised by specially trained personnel when initiating a vigorous exercise program.¹⁰⁶ The consensus

document cautions that this recommendation should not be interpreted as a restriction on participation in wheelchair sports by persons with chronic SCI. Instead, those with SCI need only satisfy the previously identified clearance issues before undertaking sports participation, and then follow-up as needed with a qualified exercise professional. Additionally, the authors of this opinion are moot in describing how long supervision is indicated once the level of conditioning has improved and adjustment to the demands of vigorous exercise has occurred.

Customizing a physical activity prescription

Once an individual with SCI has been cleared for physical activity, the next step is to generate a customized physical activity prescription. The goal of customization is to help the person with SCI develop a new, sustainable pathway to becoming physically active. The targeted physical activity “behavior” is constant across all persons with SCI, i.e. avoid inactivity by engaging in as much light/very light activity as possible; accumulate 150 minutes of moderate intensity activity weekly; and resistance train twice weekly. The programs will be customized by the pathway each person will take to increase their physical activity levels, and consider barriers they must overcome. Customization of a physical activity prescription requires engaging the individual to jointly develop a behavior change plan that empowers them to engage in the appropriate amount of physical activity. Discussion of behavior change theory, practice, and applications to improve physical activity among persons with SCI is beyond the scope of this study. However, we refer readers to the work of Arbour-Nicitopoulos, Ginis, and Latimer, who demonstrated that action-coping planning increased LTPA among persons with SCI when compared with action planning alone.¹⁰⁷ Action planning requires an individual to declare *a priori* the type, intensity, duration, days/time, and locations of the physical activity, e.g. I will propel my wheelchair (type) at a moderate intensity (intensity) for 30 minutes (duration) Monday through Friday (days) after work (time) at the local high school track (location). Action coping planning includes the action planning plus *a priori* identification of potential barriers and their solution, e.g. if rain disrupts my plan, I will propel at the local indoor mall instead of the track.

Pharmacotherapeutic approaches to management of cardiometabolic risks

In most cases, lifestyle therapies incorporating decreased caloric intake and increased daily caloric expenditure effectively serve as first-line treatments for CMS.

However, these approaches may have questionable effectiveness for persons with SCI, as loss of body fat may require unattainable or unreasonable levels of caloric restriction,⁹ and as basal and exercise-induced caloric expenditures are decreased in patients with tetraplegia because of diminished active muscle mass and adrenergic dysfunction accompanying injury above the level of spinal sympathetic outflow.¹⁰⁸ Severe caloric restriction may also lower HDL,^{79,109} making the effort counterproductive. For those in whom the first-line approaches of diet and exercise fail to modify CMS component risks, evidence-based guidelines and current practice standards recommend pharmacotherapy.^{6,110}

Weight-loss drugs

With the October 2010 withdrawal of sibutramine from the European and North American markets, orlistat (Brand names Alli and Xenical, Brentford, Middlesex, UK) became the sole drug currently approved for reduction of body mass. However, the mechanism of drug action that decreases caloric uptake by inhibiting intestinal lipase activity sometimes results in steatorrhea and socially discomforting incontinence.¹¹¹ No evidence suggests that the drug is suitable for use by those with a neurogenic bowel, or would be appropriate for use by persons with SCI.

Dysglycemia

Candidate drugs to treat dysglycemia after SCI have been reviewed by Goldberg.¹¹² Six classes of oral medication are currently approved to treat elevated blood glucose in people with type 2 diabetes: metformin (Glucophage, Princeton, NJ; Fortamet, Atlanta, GA and others), sulfonylureas (Amaryl, Bridgewater, NJ; Glucotrol, New York, NY and others), thiazolidinediones (Avandia, Brentford, Middlesex, UK and Actos, Deerfield, IL), meglitinides (Starlix, East Hanover, NJ and Prandin, Princeton, NJ), Dipeptidyl peptidase-4 inhibitors (Januvia, Whitehouse Station, NJ, USA and Onglyza, Princeton, NJ), and Glucagon-like peptide-1 receptor agonists (Byetta, San Diego, California and Victoza, Princeton, NJ). Most of the described drugs lower hemoglobin A1c levels – a surrogate for chronic glycemic control – by 0.5–2.0%, which depending on pre-treatment A1c levels above the 6.5–7% clinical target for those with diabetes mellitus may require more than one agent. Recent evidence-based guidelines, including a consensus algorithm for initiation and adjustment of therapy, identified metformin as a preferred first-line agent for lowering glycemia,¹¹³ as it is less prone to cause hypoglycemia and water retention than other drugs, and is available

in a generic formulation that favors cost-effectiveness.¹¹⁴ Use of other glycemic-lowering therapies such as sulfonylureas and meglitinides are more prone to hypoglycemia, and the alpha-glucosidase inhibitors commonly cause GI discomfort from gas, both of which make them less appealing for therapy in those with SCI. Similarly unattractive are the thiazolidinediones, which both have black box warnings for congestive heart disease, and are associated with weight gain. None of these agents have been subjected to the rigors of randomized controlled trial in persons with SCI, although no evidence suggests that either benefits or adverse effects would differ from those reported in the non-disabled population.

Dyslipidemia

Five classes of agents are currently used to treat lipid disorders occurring in the general population: hydroxymethylglutaryl-CoA (HMG-CoA) reductase inhibitors (“Statins”), niacin (as an extended-release (ER) formulation), fibric acid derivatives (i.e. fibrates), bile-acid sequestrates, and cholesterol-uptake blockers. Their expected effects are outlined in Table 4. Another treatment option involves daily high-dose (3.8 g) omega-3 FA for persons primarily having elevated fasting triglyceride levels and an atherogenic lipoprotein phenotype.¹¹⁵ Goldberg¹¹² has described suggested drug choices and nuances for medication selection in persons with SCI, and Dyson-Hudson and Nash have reviewed testing methods and systematic approaches to Adult Treatment Panel¹¹⁶ III-based treatment decision-making for their need.¹¹⁷

Need for intervention on an atherogenic lipid profile can be determined by NCEP ATP III guidelines, which base treatment on whether LDL measured in fasting blood plasma exceeds a criterion target

computed from an array of CVD risk factors and predictions.⁶ In general, an intermediate CVD risk stratification may be used to define need for treatment, which would include individuals having Framingham scores of 1%–20% in the 10-year event risk category, and whose LDL-C levels are >130 mg/dl, or >100 mg/dl in the presence of risk factors including age, hypertension, and/or cigarette smoking or high-sensitivity C-reactive protein >3 µg/l. In the general population, individuals with this profile would likely receive a statin as a first-line drug, although several shortcomings should be considered for use of these agents in persons with SCI. The most widely reported of these limitations involves myopathy,¹¹⁸ a term that describes a spectrum of muscle-related adverse events of myalgia, myositis, rhabdomyolysis, and asymptomatic increase in concentration of creatine kinase enzyme. In most cases these adverse events will be related to simple discomfort and not the more severe nephrotoxic effects of liberated myocyte components.¹¹⁹ Simple discomfort can often be controlled through less aggressive first dosing and, if needed, more conservative dose escalation.¹²⁰ As myalgia may be related to depletion of coenzyme Q₁₀ (CoQ₁₀), dietary supplementation with CoQ₁₀ has been suggested as a countermeasure to myalgia, although without a fully confirmed evidence of benefit.¹²¹ That said, even simple myalgic effects might be compelling in persons with SCI who use upper limb function to sustain routine daily activities, and may require more diligent monitoring to accompany pre-treatment and annual checks for hepatotoxicity. To date, a randomized controlled trial has not been conducted in persons with SCI that examines safety, tolerance, and effectiveness of statin monotherapy.

An alternative to statin drugs for dyslipidemia management involves nicotinic acid (niacin) in ER formulation.

Table 4 Candidate drugs for treating dyslipidemia and expected effects on key elements of the lipid profile

Drug class	Candidate drugs	TG %Δ	LDL-C %Δ	HDL-C %Δ
HMG-CoA reductase inhibitors: “Statins”	<ul style="list-style-type: none"> • Atorvastatin (Lipitor, New York, NY) • Lovastatin (Mevacor, Whitehouse Station, NJ, USA) • Pravastatin (Pravacol, Princeton, NJ) • Rasuvastatin (Crestor, Wilmington, DE), Simvastatin (Zocor, Whitehouse Station, NJ, USA) 	↓ 10–30	↓ 25–55	↑ 5–15
Cholesterol uptake blocker	<ul style="list-style-type: none"> • Ezitamibe (Zetia, Whitehouse Station, NJ, USA) 	↓ 5–15	↓ 15–20	–
Bile-acid sequestrates	<ul style="list-style-type: none"> • Cholestyramine (Questran, Spring Valley, NY) • Colesevelam (Welchol, Parsippany, NJ) • Colestipol (Colestid, New York, NY) 	↑↓ 10–20	↑↓ 20–20	–
Niacin extended release	<ul style="list-style-type: none"> • Niaspan, Abbott Park, IL, U.S.A. 	↓ 10–30	↓ 5–25	↑ 10–35
Fibrates	<ul style="list-style-type: none"> • Tricor (Fenofibrate, Abbott Park, IL) • Lopid (Gemfibrozil, New York, NY) 	↓ 30–50	↓ 0–15	↑ 5–20
Omega-3 fat*		↓ 30–50	↓ 5–15	↓ 5–10

*3.8 g daily dose.

Niacin is an older, inexpensive broad-spectrum drug that decreases concentrations of all atherogenic plasma lipids/lipoproteins and is the most effective agent for increasing HDL-C levels.¹²² In crystalline (i.e. intermediate-release) form, the drug provokes a robust cutaneous flushing, thus compromising patient tolerance when therapeutically dosed.¹²³ However, an ER formulation of niacin (Niaspan, Abbott Park, Illinois, U.S.A.)²⁹ administered with a prostaglandin antagonist (i.e. 325 mg Acetylsalicylic Acid; Aspirin) and gradual dose escalation reduces this discomfort.¹²⁴ The therapeutic response to Niacin directly remedies the CMS component risk of low HDL, and thus addresses low HDL as the most common lipid disorder sustained by persons with SCI.^{1,45,125}

Unlike other candidate drugs for treating SCI-associated dyslipidemia, ER niacin has been subjected to RCT in persons with SCI. Nash *et al.*¹²⁶ performed a randomized controlled trial enrolling persons with SCI have low plasma levels of HDL. Forty-eight weeks of treatment on a dose-escalation schedule showed significant increased fasting HDL-C levels by 24.5%, accompanied by dose-dependent decreases in the global risk predictor ratios of TC/HDL and LDL/HDL, LDL levels, and TC levels (Fig. 3). No evidence of sustained hepatotoxicity or hyperglycemia was observed. Treatment-emergent withdrawals (12.9%) accompanied flushing ($n = 1$), hypotension/pre-syncope ($n = 1$), and diarrhea ($n = 2$), although event rates were lower than those reported for the same agent when treating non-disabled individuals. Although ER niacin use requires diligence in dose escalation, pre-treatment with aspirin to suppress the flush, and abstention from spicy foods, alcohol, and hot showers in the immediate pre-treatment period, its use as a monotherapy is safe, tolerated, and effective for most persons with chronic tetraplegia, and we expect also with paraplegia.

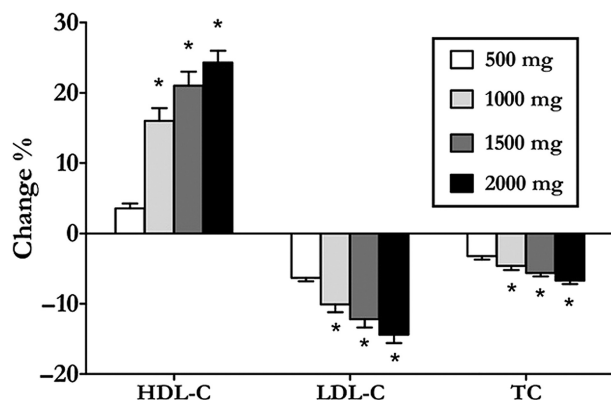


Figure 3 Dose-dependent responses of subjects with chronic tetraplegia to extended-release niacin monotherapy * $p < 0.05$, change % different from all other dosing levels.¹²⁶

Conclusions

A disconcerting number of people with SCI develop component risks for CMS as they age with their disability. These risks coalesce to comprise a frank diagnosis of the disorder in an alarming number of these individuals. Evaluation and diagnosis of the CMS now fall within the framework of an evidence-based clinical pathway that effectively assesses risk and defines uniform approaches to both individual risk containment and overall disease management. Lifestyle intervention with exercise and diet remains the cornerstone of effective treatment, and where intervention on CMS once embraced a “one-size-fits-all” plan, expanded research has provided population-specific and patient-centric approaches to both lifestyle and medical management. Exercise programs now offer greater varieties of engaging exercise that enhance activity, life-satisfaction, and health, although multi-dimensional barriers to more substantial participation still need to be surmounted. Customized programs of optimal dietary control must still be refined, although recognition of the imprudent dietary habits in this population and characterization of deficiencies represents an important first step in CMS risk containment. Behavioral approaches enhance compliance and benefit derived from both diet and exercise interventions, and may be necessary to assure that persons with SCI profit from their efforts. Evidence suggests that multi-therapy strategies will be needed to control the more challenging of component risks, such as gain in body mass, which has far reaching implications for maintenance of daily function as well as health. In cases where lifestyle approaches prove inadequate for risk management, pharmacologic control is now available through a population tested drug that is inexpensive and widely available. These customized tools will likely foster a more effective health-centered culture for stakeholders with SCI and their health professionals alike.

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References

- Nash MS, Mendez AJ. A guideline-driven assessment of need for cardiovascular disease risk intervention in persons with chronic paraplegia. *Arch Phys Med Rehabil* 2007;88(6):751–7.
- Bauman WA, Spungen AM. Coronary heart disease in individuals with spinal cord injury: assessment of risk factors. *Spinal Cord* 2008;46(7):466–76.
- Wahman K, Nash MS, Westgren N, Lewis JE, Seiger A, Levi R. Cardiovascular disease risk factors in persons with paraplegia: the Stockholm spinal cord injury study. *J Rehabil Med* 2010;42(3):272–8.
- Groah SL, Nash MS, Ward EA, Libin A, Mendez AJ, Burns P, et al. Cardiometabolic risk in community-dwelling persons with chronic spinal cord injury. *J Cardiopulmonary Rehabil Prevent*. 2011;31(2):73–80.
- Govindarajan G, Whaley-Connell A, Mugo M, Stump C, Sowers JR. The cardiometabolic syndrome as a cardiovascular risk factor. *Am J Med Sci* 2005;330(6):311–8.
- Third Report of the National Cholesterol Education Program (NCEP). Expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (adult treatment panel III) final report. *Circulation* 2002;106(25):3143–421.
- Grassi G, Seravalle G, Quarti-Trevano F, Dell’Oro R, Bombelli M, Mancia G. Metabolic syndrome and cardiometabolic risk: an update. *Blood Press* 2009;18(1–2):7–16.
- Bauman WA, Spungen AM. Metabolic changes in persons after spinal cord injury. *Phys Med Rehabil Clin N Am* 2000;11(1):109–40.
- Cowan RE, Nash MS. Cardiovascular disease, SCI and exercise: unique risks and focused countermeasures. *Disabil Rehabil* 2010;32(26):2228–36.
- Ashraf SG, David RG, Jr. Prevalence of obesity after spinal cord injury. *Top Spinal Cord Inj Rehabil* 2007;12(4):1–7.
- Buchholz AC, Bugaresti JM. A review of body mass index and waist circumference as markers of obesity and coronary heart disease risk in persons with chronic spinal cord injury. *Spinal Cord* 2005;43(9):513–8.
- Spungen AM, Adkins RH, Stewart CA, et al. Factors influencing body composition in persons with spinal cord injury: a cross-sectional study. *J Appl Physiol* 2003;95(6):2398–407.
- Duckworth WC, Solomon SS, Jallepalli P, Heckemeyer C, Finnern J, Powers A. Glucose intolerance due to insulin resistance in patients with spinal cord injuries. *Diabetes* 1980;29(11):906–10.
- Bauman WA, Spungen AM. Disorders of carbohydrate and lipid metabolism in veterans with paraplegia or quadriplegia: a model of premature aging. *Metabolism* 1994;43(6):749–56.
- Lee MY, Myers J, Hayes A, Madan S, Froelicher VF, Perkash I, et al. C-reactive protein, metabolic syndrome, and insulin resistance in individuals with spinal cord injury. *J Spinal Cord Med* 2005;28(1):20–5.
- Bauman WA, Spungen AM. Carbohydrate and lipid metabolism in chronic spinal cord injury. *J Spinal Cord Med* 2001;24(4):266–77.
- Myers J, Lee M, Kiratli J. Cardiovascular disease in spinal cord injury: an overview of prevalence, risk, evaluation, and management. *Am J Phys Med Rehabil* 2007;86(2):142–52.
- Nash MS, DeGroot J, Martinez-Arizala A, Mendez AJ. Evidence for an exaggerated postprandial lipemia in chronic paraplegia. *J Spinal Cord Med* 2005;28(4):320–5.
- Emmons RR, Garber CE, Ciriigliaro CM, Moyer JM, Kirshblum SC, Galea MD, et al. The influence of visceral fat on the postprandial lipemic response in men with paraplegia. *J Am Coll Nutr* 2010;29(5):476–81.
- Nash MS. Central nervous system: spinal cord injury. In: Frontera WR, Dawson DM, Slovik DM E, (eds.) *Exercise in rehabilitation medicine*. Champaign, IL: Human Kinetic Publishers; 2006. p. 191–205.
- Nash MS. Cardiovascular fitness after spinal cord injuries. In: Lin V, (ed.) *Spinal cord medicine*. New York, NY: Demos Medical Publications; 2002. p. 637–46.
- Frost F, Roach MJ, Kushner I, Schreiber P. Inflammatory C-reactive protein and cytokine levels in asymptomatic people with chronic spinal cord injury. *Arch Phys Med Rehabil* 2005;86(2):312–7.
- Manns PJ, McCubbin JA, Williams DP. Fitness, inflammation, and the metabolic syndrome in men with paraplegia. *Arch Phys Med Rehabil* 2005;86(6):1176–81.
- Liang H, Mojtahedi MC, Chen D, Braunschweig CL. Elevated c-reactive protein associated with decreased high-density lipoprotein cholesterol in men with spinal cord injury. *Arch Phys Med Rehabil* 2008;89(1):36–41.
- Vasudevan AR, Ballantyne CM. Cardiometabolic risk assessment: an approach to the prevention of cardiovascular disease and diabetes mellitus. *Clin Cornerstone* 2005;7(2–3):7–16.
- Ginsberg HN, Stalenhoef AF. The metabolic syndrome: targeting dyslipidaemia to reduce coronary risk. *J Cardiovasc Risk* 2003;10(2):121–8.
- Groah SL, Libin A, Lauderdale M, Kroll T, DeJong G, Hsieh J. Beyond the evidence-based practice paradigm to achieve best practice in rehabilitation medicine: a clinical review. *PMR* 2009;1(10):941–50.
- McKenney JM. Update on the National Cholesterol Education Program Adult Treatment Panel III guidelines: getting to goal. *Pharmacotherapy* 2003;23(9 Pt 2):26S–33S.
- Feasel S, Groah S. The impact of diet on cardiovascular disease risk in individuals with spinal cord injury. *Top Spinal Cord Inj Rehabil* 2009;14(3):56–68.
- Lake A, Townshend T. Obesogenic environments: exploring the built and food environments. *J R Soc Promot Health* 2006;126(6):262–7.
- Groah SL, Nash MS, Ljungberg IH, Libin A, Hamm LF, Ward E, et al. Nutrient intake and body habitus after spinal cord injury: an analysis by sex and level of injury. *J Spinal Cord Med* 2009;32(1):25–33.
- U.S. Department of Agriculture and U.S. Department of Health and Human Services. *Dietary guidelines for Americans*. 7th ed. Washington, DC: Government Printing Office; 2010. p. 112.
- Walters JL, Buchholz AC, Martin Ginis KA. Evidence of dietary inadequacy in adults with chronic spinal cord injury. *Spinal Cord* 2009;47(4):318–22.
- Perret C, Stoffel-Kurt N. Comparison of nutritional intake between individuals with acute and chronic spinal cord injury. *J Spinal Cord Med* 2011;34(6):569–75.
- Edwards LA, Bugaresti JM, Buchholz AC. Visceral adipose tissue and the ratio of visceral to subcutaneous adipose tissue are greater in adults with than in those without spinal cord injury, despite matching waist circumferences. *Am J Clin Nutr* 2008;87(3):600–7.
- Tomey KM, Chen DM, Wang X, Braunschweig CL. Dietary intake and nutritional status of urban community-dwelling men with paraplegia. *Arch Phys Med Rehabil* 2005;86(4):664–71.
- Levine AM, Nash MS, Green BA, Shea JD, Aronica MJ. An examination of dietary intakes and nutritional status of chronic healthy spinal cord injured individuals. *Paraplegia* 1992;30(12):880–9.
- Aquilani R, Boschi F, Contardi A, Pistarini C, Achilli MP, Fizzotti G, et al. Energy expenditure and nutritional adequacy of rehabilitation paraplegics with asymptomatic bacteriuria and pressure sores. *Spinal Cord* 2001;39(8):437–41.
- Lee BY, Agarwal N, Corcoran L, Thoden WR, Del Guercio LR. Assessment of nutritional and metabolic status of paraplegics. *J Rehabil Res Dev* 1985;22(3):11–7.
- Sabour H, Javidan AN, Vafa MR, Shidfar F, Nazari M, Saberi H, et al. Calorie and macronutrients intake in people with spinal cord injuries: an analysis by sex and injury-related variables. *Nutrition* 2012;28(2):143–7.
- Peiffer SC, Blust P, Leyson JF. Nutritional assessment of the spinal cord injured patient. *J Am Diet Assoc* 1981;78(5):501–5.
- Barboriak JJ, Rooney CB, El Ghatit AZ, Spuda K, Anderson AJ. Nutrition in spinal cord injury patients. *J Am Paraplegia Soc* 1983;6(2):32–6.
- Aghaiehsavari M, Noroozianavval M, Veisi P, Parizad R, Samadikhah J. Cardiovascular disease risk factors in patients with confirmed cardiovascular disease. *Saudi Med J* 2006;27(9):1358–61.
- Moussavi RM, Ribas-Cardus F, Rintala DH, Rodriguez GP. Dietary and serum lipids in individuals with spinal cord injury living in the community. *J Rehabil Res Dev* 2001;38(2):225–33.
- Zlotolow SP, Levy E, Bauman WA. The serum lipoprotein profile in veterans with paraplegia: the relationship to nutritional

- factors and body mass index. *J Am Paraplegia Soc* 1992;15(3):158–62.
- 46 Hooper L, Summerbell CD, Thompson R, Sills D, Roberts FG, Moore HJ, *et al*. Reduced or modified dietary fat for preventing cardiovascular disease. *Cochrane Database Syst Rev* 2012;5:CD002137.
- 47 Schrauwen P, Westerterp KR. The role of high-fat diets and physical activity in the regulation of body weight. *Br J Nutr* 2000;84(4):417–27.
- 48 Knight KH, Buchholz AC, Martin Ginis KA, Goy RE. Leisure-time physical activity and diet quality are not associated in people with chronic spinal cord injury. *Spinal Cord* 2011;49(3):381–5.
- 49 Battista P, Di Primio R, Di Luzio A, Nubile G, Di Tano G. Correlations between dietetic fiber and serum levels of total cholesterol and HDL-cholesterol. *Boll Soc Ital Biol Sper* 1983;59(1):83–6.
- 50 Brown L, Rosner B, Willett WW, Sacks FM. Cholesterol-lowering effects of dietary fiber: a meta-analysis. *Am J Clin Nutr* 1999;69(1):30–42.
- 51 Mietus-Snyder ML, Shigenaga MK, Suh JH, Shenvi SV, Lal A, McHugh T, *et al*. A nutrient-dense, high-fiber, fruit-based supplement bar increases HDL cholesterol, particularly large HDL, lowers homocysteine, and raises glutathione in a 2-wk trial. *FASEB J* 2012;26(8):3515–27. Epub 2012 May 1.
- 52 Reyna-Villasamil N, Bermudez-Pirela V, Mengual-Moreno E, Arias N, Cano-Ponce C, Leal-Gonzalez E, *et al*. Oat-derived beta-glucan significantly improves HDLC and diminishes LDLc and non-HDL cholesterol in overweight individuals with mild hypercholesterolemia. *Am J Ther* 2007;14(2):203–12.
- 53 Cameron KJ, Nyulasi IB, Collier GR, Brown DJ. Assessment of the effect of increased dietary fibre intake on bowel function in patients with spinal cord injury. *Spinal Cord* 1996;34(5):277–83.
- 54 Krassioukov A, Eng JJ, Claxton G, Sakakibara BM, Shum S. Neurogenic bowel management after spinal cord injury: a systematic review of the evidence. *Spinal Cord* 2010;48(10):718–33.
- 55 Laven GT, Huang CT, DeVivo MJ, Stover SL, Kuhlemeier KV, Fine PR. Nutritional status during the acute stage of spinal cord injury. *Arch Phys Med Rehabil* 1989;70(4):277–82.
- 56 Moussavi RM, Garza HM, Eisele SG, Rodriguez G, Rintala DH. Serum levels of vitamins A, C, and E in persons with chronic spinal cord injury living in the community. *Arch Phys Med Rehabil* 2003;84(7):1061–7.
- 57 Berger D. Dietary management of the paraplegic patient. *Can Serv Med J* 1954;10(1):65–70.
- 58 Khandare AL, Shankar NH, Kalyanasundaram S, Rao GS. Effect of calcium deficiency induced by fluoride intoxication on lipid metabolism in rabbits. *Fluoride* 2007;40(3):184–9.
- 59 Chaudhary DP, Sharma R, Bansal DD. Implications of magnesium deficiency in type 2 diabetes: a review. *Biol Trace Elem Res* 2010;134(2):119–29.
- 60 Olson ML, Maalouf NM, Oden JD, White PC, Hutchison MR. Vitamin D deficiency in obese children and its relationship to glucose homeostasis. *J Clin Endocrinol Metab* 2012;97(1):279–85.
- 61 Fattoretti P, Bertoni-Freddari C, Casoli T, Di Stefano G, Solazzi M, Giorgetti B. Decreased expression of glucose transport protein (Glut3) in aging and vitamin E deficiency. *Ann N Y Acad Sci* 2002;973:293–6.
- 62 Frikke-Schmidt H, Lykkesfeldt J. Role of marginal vitamin C deficiency in atherogenesis: in vivo models and clinical studies. *Basic Clin Pharmacol Toxicol* 2009;104(6):419–33.
- 63 Grungreiff K, Reinhold D. Liver cirrhosis and ‘liver’ diabetes mellitus are linked by zinc deficiency. *Med Hypotheses* 2005;64(2):316–7.
- 64 Kaya A, Altiner A, Ozpinar A. Effect of copper deficiency on blood lipid profile and haematological parameters in broilers. *J Vet Med A Physiol Pathol Clin Med* 2006;53(8):399–404.
- 65 Larrieta E, Vega-Monroy ML, Vital P, Aguilera A, German MS, Hafidi ME, *et al*. Effects of biotin deficiency on pancreatic islet morphology, insulin sensitivity and glucose homeostasis. *J Nutr Biochem* 2012;23(4):392–99.
- 66 Matthews KA, Rhoten WB, Driscoll HK, Chertow BS. Vitamin A deficiency impairs fetal islet development and causes subsequent glucose intolerance in adult rats. *J Nutr* 2004;134(8):1958–63.
- 67 McRae MP. Vitamin C supplementation lowers serum low-density lipoprotein cholesterol and triglycerides: a meta-analysis of 13 randomized controlled trials. *J Chiropr Med* 2008;7(2):48–58.
- 68 Nielsen FH, Milne DB, Klevay LM, Gallagher S, Johnson L. Dietary magnesium deficiency induces heart rhythm changes, impairs glucose tolerance, and decreases serum cholesterol in postmenopausal women. *J Am Coll Nutr* 2007;26(2):121–32.
- 69 Reiterer G, MacDonald R, Browning JD, Morrow J, Matveev SV, Daugherty A, *et al*. Zinc deficiency increases plasma lipids and atherosclerotic markers in LDL-receptor-deficient mice. *J Nutr* 2005;135(9):2114–8.
- 70 Rowe JW, Tobin JD, Rosa RM, Andres R. Effect of experimental potassium deficiency on glucose and insulin metabolism. *Metabolism* 1980;29(6):498–502.
- 71 Yoshida M, Jacques PF, Meigs JB, Saltzman E, Shea MK, Gundberg C, *et al*. Effect of vitamin K supplementation on insulin resistance in older men and women. *Diabetes Care* 2008;31(11):2092–6.
- 72 Langer RD, Criqui MH, Reed DM. Lipoproteins and blood pressure as biological pathways for effect of moderate alcohol consumption on coronary heart disease. *Circulation* 1992;85(3):910–15.
- 73 Corrao G, Rubbiati L, Bagnardi V, Zambon A, Poikolainen K. Alcohol and coronary heart disease: a meta-analysis. *Addiction* 2000;95(10):1505–23.
- 74 Wakabayashi I. Increased body mass index modifies associations between alcohol intake and blood cholesterol profile. *Eur J Clin Invest* 2012;42(2):179–85.
- 75 Saunders LL, Krause JS. Psychological factors affecting alcohol use after spinal cord injury. *Spinal Cord* 2011;49(5):637–42.
- 76 Tate DG, Forchheimer MB, Krause JS, Meade MA, Bombardier CH. Patterns of alcohol and substance use and abuse in persons with spinal cord injury: risk factors and correlates. *Arch Phys Med Rehabil* 2004;85(11):1837–47.
- 77 Bombardier CH, Rimmele CT. Alcohol use and readiness to change after spinal cord injury. *Arch Phys Med Rehabil* 1998;79(9):1110–15.
- 78 Phillips E, Gater DR. A practical Approach for the nutritional management of obesity in spinal cord injury. *Top Spinal Cord Inj Rehabil* 2007;12(4):64–75.
- 79 Szlachcic Y, Adkins RH, Adal T, Yee F, Bauman W, Waters RL. The effect of dietary intervention on lipid profiles in individuals with spinal cord injury. *J Spinal Cord Med* 2001;24(1):26–9.
- 80 Chen Y, Henson S, Jackson AB, Richards JS. Obesity intervention in persons with spinal cord injury. *Spinal Cord* 2006;44(2):82–91.
- 81 Liusuwan RA, Widman LM, Abresch RT, Styne DM, McDonald CM. Body composition and resting energy expenditure in patients aged 11 to 21 years with spinal cord dysfunction compared to controls: comparisons and relationships among the groups. *J Spinal Cord Med* 2007;30(Suppl. 1):105–11.
- 82 Zemper ED, Tate DG, Roller S, Forchheimer M, Chiodo A, Nelson VS, *et al*. Assessment of a holistic wellness program for persons with spinal cord injury. *Am J Phys Med Rehabil* 2003;82(12):957–68. Quiz 969–71.
- 83 Emon ST, Irban AG, Bozkurt SU, Akakin D, Konya D, Ozgen S. Effects of parenteral nutritional support with fish-oil emulsion on spinal cord recovery in rats with traumatic spinal cord injury. *Turk Neurosurg* 2011;21(2):197–202.
- 84 Huang WL, King VR, Curran OE, Dyall SC, Ward RE, Lal N, *et al*. A combination of intravenous and dietary docosahexaenoic acid significantly improves outcome after spinal cord injury. *Brain* 2007;130(Pt 11):3004–19.
- 85 Javierre C, Vidal J, Segura R, Medina J, Garrido E. Continual supplementation with n-3 fatty acids does not modify plasma lipid profile in spinal cord injury patients. *Spinal Cord* 2005;43(9):527–30.
- 86 Kris-Etherton PM, Harris WS, Appel LJ. Fish consumption, fish oil, omega-3 fatty acids, and cardiovascular disease. *Circulation* 2002;106(21):2747–57.
- 87 Harris WS. n-3 fatty acids and serum lipoproteins: human studies. *Am J Clin Nutr* 1997;65(5 Suppl.):1645S–54S.
- 88 Kris-Etherton PM, Harris WS, Appel LJ. Omega-3 fatty acids and cardiovascular disease: new recommendations from the American Heart Association. *Arterioscler Thromb Vasc Biol* 2003;23(2):151–2.

- 89 Tasiemski T, Bergstrom E, Savic G, Gardner BP. Sports, recreation and employment following spinal cord injury—a pilot study. *Spinal Cord* 2000;38(3):173–84.
- 90 Ginis KA, Arbour-Nicitopoulos KP, Latimer AE, Buchholz AC, Bray SR, Craven BC, *et al.* Leisure time physical activity in a population-based sample of people with spinal cord injury part II: activity types, intensities, and durations. *Arch Phys Med Rehabil* 2010;91(5):729–33.
- 91 Ginis KA, Latimer AE, Arbour-Nicitopoulos KP, Buchholz AC, Bray SR, Craven BC, *et al.* Leisure time physical activity in a population-based sample of people with spinal cord injury part I: demographic and injury-related correlates. *Arch Phys Med Rehabil* 2010;91(5):722–8.
- 92 Centers for Disease Control and Prevention. National Center for Health Statistics. Health Indicators Warehouse. 2009–2010. Available from: http://healthindicators.gov/Indicators/Leisure-time-physical-activity-none-percent_1313/National_0/Profile/Data.
- 93 El-Sayed MS, Younesian A. Lipid profiles are influenced by arm cranking exercise and training in individuals with spinal cord injury. *Spinal Cord* 2005;43(5):299–305.
- 94 Nash MS, Jacobs PL, Mendez AJ, Goldberg RB. Circuit resistance training improves the atherogenic lipid profile in persons with chronic paraplegia. *J Spinal Cord Med* 2001;24(1):2–9.
- 95 Hooker SP, Wells CL. Effects of low- and moderate-intensity training in spinal cord-injured persons. *Med Sci Sports Exerc* 1989;21(1):18–22.
- 96 de Groot PC, Hjeltnes N, Heijboer AC, Stal W, Birkeland K. Effect of training intensity on physical capacity, lipid profile and insulin sensitivity in early rehabilitation of spinal cord injured individuals. *Spinal Cord* 2003;41(12):673–9.
- 97 Dallmeijer AJ, Hopman MT, van der Woude LH. Lipid, lipoprotein, and apolipoprotein profiles in active and sedentary men with tetraplegia. *Arch Phys Med Rehabil* 1997;78(11):1173–6.
- 98 Janssen TW, van Oers CA, van Kamp GJ, TenVoorde BJ, van der Woude LH, Hollander AP. Coronary heart disease risk indicators, aerobic power, and physical activity in men with spinal cord injuries. *Arch Phys Med Rehabil* 1997;78(7):697–705.
- 99 Buchholz AC, Martin Ginis KA, Bray SR, Craven BC, Hicks AL, Hayes KC, *et al.* Greater daily leisure time physical activity is associated with lower chronic disease risk in adults with spinal cord injury. *Appl Physiol Nutr Metab* 2009;34(4):640–7.
- 100 de Groot S, Dallmeijer AJ, Post MW, Angenot EL, van den Berg-Emons RJ, van der Woude LH. Prospective analysis of lipid profiles in persons with a spinal cord injury during and 1 year after inpatient rehabilitation. *Arch Phys Med Rehabil* 2008;89(3):531–7.
- 101 Carlson KF, Wilt TJ, Taylor BC, Goldish GD, Niewoehner CB, Shamlivan TA, *et al.* Effect of exercise on disorders of carbohydrate and lipid metabolism in adults with traumatic spinal cord injury: systematic review of the evidence. *J Spinal Cord Med* 2009;32(4):361–78.
- 102 Ginis KA, Hicks AL, Latimer AE, Warburton DE, Bourne C, Ditor DS, *et al.* The development of evidence-informed physical activity guidelines for adults with spinal cord injury. *Spinal Cord* 2011;49(11):1088–96.
- 103 U.S. Department of Health and Human Services. Physical Activity Guidelines for Americans. Centers for Disease Control and Prevention, National Center for Health Statistics. 2008. Available from: www.hhs.gov.
- 104 Canadian Society for Exercise Physiology, Canadian Physical Activity Guidelines, 2012 Scientific Statements. Available from: www.csep.ca/guidelines.
- 105 Manns PJ, Dunstan DW, Owen N, Healy GN. Addressing the nonexercise part of the activity continuum: a more realistic and achievable approach to activity programming for adults with mobility disability? *Phys Ther* 2012;92(4):614–25.
- 106 Warburton DE, Gledhill N, Jamnik VK, Bredin SS, McKenzie DC, Stone J, *et al.* Evidence-based risk assessment and recommendations for physical activity clearance: Consensus Document 2011 (1) (1) This paper is one of a selection of papers published in this Special Issue, entitled Evidence-based risk assessment and recommendations for physical activity clearance, and has undergone the Journal's usual peer review process. *Appl Physiol Nutr Metab* 2011;36(Suppl. 1):S266–98.
- 107 Arbour-Nicitopoulos KP, Ginis KA. Universal accessibility of 'accessible' fitness and recreational facilities for persons with mobility disabilities. *Adapt Phys Activ Q* 2011;28(1):1–15.
- 108 Nash MS. Exercise as a health-promoting activity following spinal cord injury. *J Neurol Phys Ther* 2005;29(2):87–103, 106.
- 109 Weltman A, Matter S, Stamford BA. Caloric restriction and/or mild exercise: effects on serum lipids and body composition. *Am J Clin Nutr* 1980;33(5):1002–9.
- 110 Lifestyle and risk factor management and use of drug therapies in coronary patients from 15 countries; principal results from EUROASPIRE II Euro Heart Survey Programme. *Eur Heart J* 2001;22(7):554–72.
- 111 Korpelman P, Groot Gde H, Rissanen A, Rossner S, Toubro S, Palmer R, *et al.* Weight loss, HbA1c reduction, and tolerability of cetilistat in a randomized, placebo-controlled phase 2 trial in obese diabetics: comparison with orlistat (Xenical). *Obesity* 2010;18(1):108–15.
- 112 Goldberg R. Guideline-driven Intervention on SCI-Associated dyslipidemia, metabolic syndrome, and glucose intolerance using pharmacological agents. *Top Spinal Cord Inj Rehabil* 2009;14(3):46–57.
- 113 Nathan DM, Buse JB, Davidson MB, Ferrannini E, Holman RR, Sherwin R, *et al.* Medical management of hyperglycaemia in type 2 diabetes mellitus: a consensus algorithm for the initiation and adjustment of therapy: a consensus statement from the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetologia* 2009;52(1):17–30.
- 114 Bolen S, Feldman L, Vassy J, Wilson L, Yeh HC, Marinopoulos S, *et al.* Systematic review: comparative effectiveness and safety of oral medications for type 2 diabetes mellitus. *Ann Intern Med* 2007;147(6):386–99.
- 115 Goldberg RB, Sabharwal AK. Fish oil in the treatment of dyslipidemia. *Curr Opin Endocrinol Diabetes Obes* 2008;15(2):167–74.
- 116 Khachatryan V, Sirunyan AM, Tumasyan A, Adam W, Bergauer T, Dragicevic M, *et al.* Search for quark compositeness with the dijet centrality ratio in pp collisions at radicals = 7 TeV. *Phys Rev Lett* 2010;105(2):022002. Epub 2010 Jul 6.
- 117 Dyson-Hudson T, Nash MS. Guideline-driven assessment of cardiovascular disease and related risks after spinal cord injury. *Top Spinal Cord Inj Rehabil* 2009;14:32–45.
- 118 Farmer JA. Statins and myotoxicity. *Curr Atheroscler Rep* 2003;5(2):96–100.
- 119 Klopstock T. Drug-induced myopathies. *Curr Opin Neurol* 2008;21(5):590–5.
- 120 Nash MS, Goldberg RB. Higher starting doses of atorvastatin may reduce LDL-cholesterol levels more than lower doses. *Commentary. Evid Based Cardiovasc Med* 2005;9(2):98–101.
- 121 Marloff L, Thompson PD. The role of coenzyme Q10 in statin-associated myopathy: a systematic review. *J Am Coll Cardiol* 2007;49(23):2231–7.
- 122 Goldberg AC. Clinical trial experience with extended-release niacin (Niaspan): dose-escalation study. *Am J Cardiol* 1998;82(12A):35U–8U.
- 123 Knopp RH, Ginsberg J, Albers JJ, Hoff C, Ogilvie JT, Warnick GR, *et al.* Contrasting effects of unmodified and time-release forms of niacin on lipoproteins in hyperlipidemic subjects: clues to mechanism of action of niacin. *Metabolism* 1985;34(7):642–50.
- 124 Morgan JM, Capuzzi DM, Guyton JR. A new extended-release niacin (Niaspan): efficacy, tolerability, and safety in hypercholesterolemic patients. *Am J Cardiol* 1998;82(12A):29U–34U.
- 125 Brenes G, Dearwater S, Shapera R, LaPorte RE, Collins E. High density lipoprotein cholesterol concentrations in physically active and sedentary spinal cord injured patients. *Arch Phys Med Rehabil* 1986;67(7):445–50.
- 126 Nash MS, Lewis JE, Dyson-Hudson TA, Szlachcic Y, Yee F, Mendez AJ, *et al.* Safety, tolerance, and efficacy of extended-release niacin monotherapy for treating dyslipidemia risks in persons with chronic tetraplegia: a randomized multicenter controlled trial. *Arch Phys Med Rehabil* 2011;92(3):399–410.